

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

ALEXANDRE PELLETIER, Individually
and on Behalf of All Others Similarly
Situating,

Plaintiffs,

v.

ENDO INTERNATIONAL PLC, RAJIV
KANISHKA LIYANAARCHCHIE DE
SILVA, SUKETU P. UPADHYAY, and
PAUL V. CAMPANELLI,

Defendants.

No. 2:17-cv-05114-JRP

ORAL ARGUMENT REQUESTED

REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF DEFENDANTS'
MOTION TO DISMISS THE AMENDED COMPLAINT

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Preliminary Statement

Plaintiff attempts to plead a securities fraud claim against Endo and its senior executives by making it seem as though this case can just piggyback on an antitrust lawsuit brought by a group of state attorneys general and a DOJ investigation concerning generic pharmaceutical pricing. Not only is this far from enough to plead a securities fraud claim, but in seeking to avoid dismissal, Plaintiff seriously mischaracterizes these government proceedings and their relevance to this case.

Endo is not one of the 20 defendants in the State AGs' lawsuit. Although an indirect subsidiary of Endo (Par Pharmaceutical Companies, Inc.) is a defendant in that case, the State AGs' allegations as to Par relate exclusively to alleged conduct *before* Endo acquired Par, and to a product (doxycycline monohydrate) that is *not* one of the 13 products that the Plaintiff in this case characterizes as "Inflated Drugs." (See ¶¶ 98-145.) The State AGs' allegations do nothing to support Plaintiff's theory that Endo engaged in illegal pricing of entirely different products. (Opp. at 27-29.) Even if the State AGs eventually were to prove *every* allegation they have made, that would not establish illegal pricing of *any* product at issue in *this* case.

Plaintiff's reliance on the DOJ investigation fares no better. The law is clear that the existence of an investigation provides no basis to infer misconduct. (Def. Br. at 7.) Plaintiff's reference to the DOJ's intervention in civil antitrust litigation against a number of generic pharmaceutical companies is particularly irrelevant. (Opp. at 44.) Plaintiff fails to inform this Court that the purpose of the DOJ's intervention was simply to *stay* discovery in the private cases (to avoid potential interference with the DOJ investigation), and that the DOJ's motion to intervene took no position on the merits of the cases and did not mention Endo (or Par) at all. It is of no consequence here.

Other plaintiffs have tried—and failed—to transform government litigation and price-fixing investigations into securities fraud claims. Judge Beetlestone recently dismissed such claims based on the same State AGs’ case in *Utesch v. Lannett Co., Inc.*, 316 F. Supp. 3d 895 (E.D. Pa. 2018), a well-reasoned decision discussed throughout Defendants’ opening brief. Tellingly, Plaintiff has nothing to say about *Utesch* until the end of its brief and then only quibbles with its analysis of confidential witnesses. (Opp. at 38-39.) Similar claims—also referencing the State AGs’ suit, *see* Dkt. No. 32—were also dismissed in *Fleming v. Impax Corp.*, No. 16-cv-06557-HSG, 2018 WL 4616291 (N.D. Cal. Sept. 7, 2018).

Plaintiff instead relies heavily on three cases that are not at all like this case. Those cases—*In re Mylan N.V. Sec. Litig.*, 2018 WL 1595985 (S.D.N.Y. Mar. 28, 2018); *Roofers’ Pension Fund v. Papa*, 2018 WL 3601229 (D.N.J. July 27, 2018) (“*Perrigo*”); and *Speakes v. Taro Pharm. Indus., Ltd.*, 2018 WL 4572987 (S.D.N.Y. Sept. 24, 2018)—each found securities fraud claims adequately pled where plaintiffs had alleged facts that, if proven, could support a plausible inference that the defendant companies had conspired to fix prices. No such facts are pled here against Endo.

It simply is not the law that a securities fraud claim can automatically be maintained against any company that finds itself (or, in Endo’s case, an indirect subsidiary) named as a defendant in an antitrust lawsuit—even where, unlike here, the securities case and the antitrust case involve the same products. Moreover, even under Plaintiff’s own case law, pleading a securities fraud claim predicated on alleged illegal price-fixing requires facts sufficient to support a plausible inference that the challenged pricing actions were the result of an unlawful conspiracy, as opposed to independent business decisions—as well as facts establishing that the nondisclosure of the alleged conspiracy was false or misleading *and* scienter as to each

defendant. The Amended Complaint pleads no such facts here. It should be dismissed, with prejudice.

Argument

I. PLAINTIFF FAILS TO ALLEGE A FALSE OR MISLEADING STATEMENT

Plaintiff argues it has satisfied the misstatement element of its claim in two ways. First, it points to its (wholly inadequate) allegations that Endo engaged in “illegal” price-fixing, and that the failure to disclose this price-fixing was materially misleading. (Opp. at 22-30.) Because Defendants’ opening brief demonstrates that Plaintiff has not pled facts plausibly establishing a price-fixing conspiracy, Plaintiff’s opposition brief shifts its focus to an underdeveloped alternate theory—that Defendants made misstatements about Endo’s income, market, and pricing “independent” of illegal pricing conduct. (*Id.* at 14-21.) Neither theory supports a claim for securities fraud.

A. Plaintiff Fails To Adequately Allege A Price-Fixing Conspiracy

As explained in Defendants’ opening brief, to state a claim based on an alleged failure to disclose an illegal price-fixing conspiracy, Third Circuit law requires Plaintiff to plead facts plausibly establishing that Endo engaged in illegal price-fixing. (Def. Br. at 9.) Unless the underlying price-fixing conspiracy is adequately alleged, there can be no securities claim for failure to disclose it.

Plaintiff contends that the market for each product at issue in this case “was an oligopoly controlled by a handful of manufacturers.” (§ 155.) The U.S. Supreme Court and the Third Circuit have held that, in oligopolistic markets, it can be an entirely rational business decision for a company acting unilaterally to raise its price when one or more competitors do so (*i.e.*, “conscious parallelism” or “parallel pricing”). *See Brooke Grp. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 227 (1993); Opp. at 10-12 (citing cases). Such “conscious parallelism” is

“a common reaction of ‘firms in a concentrated market [that] recognize their shared economic interests and their interdependence with respect to price and output decisions,’ is ‘not in itself unlawful,’” and thus does not support a plausible inference of conspiracy. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 553-54 (2007) (citation omitted); accord *Burtch v. Milberg Factors, Inc.*, 662 F.3d 212, 226-27 (3d Cir. 2011) (same); *In re Chocolate Confectionary Antitrust Litig.*, 801 F.3d 383, 397 (3d Cir. 2015) (“conscious parallelism . . . can be a necessary fact of life in oligopolies”) (citation and quotation marks omitted).

As a result, and as Plaintiff now concedes, to plead an unlawful price-fixing conspiracy, plaintiffs must allege more than parallel pricing. (Opp. at 23.) In particular, they must plead parallel pricing plus other facts sufficient to support a plausible inference of a conspiracy—that the defendant’s pricing actions were the result of an agreement rather than a unilateral business decision. *Twombly*, 550 U.S. at 556. Depending on the facts and circumstances, these other factors (sometimes called “plus factors”) could include: (1) a “motive to enter into a price-fixing conspiracy,” (2) actions “contrary to [the defendant’s independent] interests,” and (3) “traditional conspiracy” evidence. *Chocolate Confectionary*, 801 F.3d at 397 (citing *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 322 (3d Cir. 2010).) Such factors help “ensure that courts punish concerted action—an actual agreement [to fix prices]—instead of the unilateral, independent conduct of competitors.” *Id.* at 398 (citation omitted); accord *Twombly*, 550 U.S. at 554 (noting “the ambiguity of the behavior” in parallel pricing, as “consistent with conspiracy” but also with independent “rational and competitive business strategy”). Plaintiff does not come close to pleading facts plausibly suggesting conspiracy. It therefore cannot maintain a securities fraud claim predicated on the notion that Endo failed to disclose alleged illegal price-fixing.

1. Plaintiff's Theories Of Motive And Self-Interest Are Inadequate

Plaintiff argues that motive and actions against self-interest are present here—(Opp. at 24-25)—but courts, including the Third Circuit, have repeatedly held that these factors (even if adequately pled) are not necessarily enough to support a plausible inference of conspiracy. With respect to “motive,” courts of course recognize that “all entrepreneurs have a legitimate understandable motive to increase profits,” and therefore that sort of motive (which is all Plaintiff alleges here) is insufficient. *Burtch*, 662 F.3d at 229 (quoting *In re Baby Food Antitrust Litig.*, 166 F.3d 112, 137 (3d Cir. 1999)).

The actions against self-interest factor “means behavior that is inconsistent with a competitive market.” *Chocolate Confectionary*, 397 F.3d at 399. But Plaintiff alleges that the relevant markets are oligopolistic, (¶ 155), and in such a market follow-the-leader pricing does not suggest conspiracy. Third Circuit law recognizes that competing for market share instead of raising prices, as Plaintiff argues Endo should have done, “is just one rational response that an oligopolist can take, a fact acknowledged by economists.” *See Chocolate Confectionary*, 397 F.3d at 401. Raising price is also an economically rational act by a company acting unilaterally. *See id.* at 397-98.

Because both a motive to make money and follow-the-leader pricing are inherent in oligopolistic markets, the Third Circuit has held that those facts *do not* support a plausible inference of conspiracy in such markets. *See id.* at 398, 400. They are likewise insufficient here, where Plaintiff’s theory is that an indirect subsidiary of Endo followed other companies’ price increases and made millions of dollars as a result. (¶¶ 2, 65-66, 96.) The controlling case law above establishes that the allegations on which Plaintiff relies are entirely consistent with a company unilaterally acting in its own independent self-interest.

Plaintiff cites no antitrust case in which motive and follow-the-leader pricing alone have been sufficient to sustain a claim of anticompetitive conduct in an oligopolistic market. Instead, Plaintiff relies on three cases—none controlling this Court—that are readily distinguishable. Indeed, the first case, *In re Propranolol Antitrust Litigation*, 249 F. Supp. 3d 712 (S.D.N.Y. 2017), expressly rejects Third Circuit law on these issues as “not binding.” *Id.* at 719 (citation omitted). Plaintiff’s other cases, *Perrigo* and *Mylan*, accept bare allegations of motive and actions against self-interest with little or no analysis, ignoring the well-established principle that conclusory assertions should be ignored on a motion to dismiss. *Perrigo*, 2018 WL 3601229, at *11; *Mylan*, 2018 WL 1595985, at *16-17. Neither case addresses, or even acknowledges, the Supreme Court and Third Circuit law holding that parallel price increases are “in line with a wide swath of rational and competitive business strategy unilaterally prompted by common perceptions of the market,” *Twombly*, 550 U.S. at 554, and that raising prices can be a rational and lawful unilateral response to others’ price increases. *Chocolate Confectionary*, 801 F.3d at 397-98.

Plaintiff’s characterization of the law would render virtually every company in an oligopolistic market liable for rational pricing decisions inherent to that market. That is not the law, and it is *exactly* the outcome the Third Circuit has cautioned against. *Id.* at 397-98.¹

¹ Plaintiff tries to distinguish *Chocolate Confectionary* as an appeal from summary judgment, without further explanation. (Opp. at 25 n.12.) To the extent Plaintiff suggests that it is not relevant to this motion to dismiss, that is a *non sequitur*. That case is cited for its controlling *law*, which plainly applies here, not its facts, and the Supreme Court has held that a complaint must be dismissed if its factual allegations amount to mere parallel conduct. *Twombly*, 550 U.S. at 553-54. In any case, the PSLRA and Rule 9(b) require Plaintiff to plead particularized *facts* to establish unlawful pricing, which it does not do. Plaintiff’s unexplained efforts to distinguish other Third Circuit cases in the same footnote are similarly unavailing.

2. Plaintiff Offers No Traditional Factual Allegations Of A Conspiracy

As the Third Circuit has explained, “traditional conspiracy” evidence—facts establishing that “defendants got together and exchanged assurances of common action or otherwise adopted a common plan”—could support a plausible inference of conspiracy. *Chocolate Confectionary*, 801 F.3d at 398; *accord Brunson Commc’ns, Inc. v. Arbitron, Inc.*, 239 F. Supp. 2d 550, 559 (E.D. Pa. 2002) (“The ‘very essence’” of a price-fixing “claim is ‘the existence of an agreement’”) (citation omitted). But Plaintiff can point to no such facts here.

Instead, Plaintiff relies on mere “opportunity to collude” (Opp. at 10), which is insufficient. *Petruzzi’s IGA Supermarkets, Inc. v. Darling-Del. Co. Inc.*, 998 F.2d 1224, 1235 (3d Cir. 1993) (“[P]roof of opportunity to conspire, without more, will not sustain an inference that a conspiracy has taken place.”). While Plaintiff points to Endo executives’ attendance at industry conferences, it does not allege that they met with competitors, let alone agreed to raise prices of the 13 alleged “Inflated Drugs,” at those conferences. None of Plaintiff’s confidential witnesses (“CWs”) make such an allegation, either. And even if they had, without facts showing that such meetings or communications actually “led to an illegal agreement,” their allegations are meaningless. *Burtch*, 662 F.3d at 228 (citation omitted).

Unable to allege the requisite facts, Plaintiff resorts to arguing that in other litigation involving different products “State AGs have specifically alleged that such interfirm conferences were in fact used by generic drug manufacturers to facilitate agreements to fix prices and allocate markets.” (Opp. at 27, 28.) But the State AGs’ case *does not name Endo as a defendant or involve any of the same products as this case. See In re Generic Pharmaceuticals Pricing*

Antitrust Litig., No. 17-CV-03768 (E.D. Pa.) (“*State AG Antitrust Litig.*”), Dkt. No. 14. The allegations made by the State AGs have no bearing on this case whatsoever.²

Plaintiff’s reliance on “law enforcement investigations” is likewise misplaced. (Opp. at 28.) While Plaintiff asserts that the Connecticut Attorney General subpoenaed Endo concerning four of the products at issue in this case as part of an investigation preceding the State AGs’ lawsuit (Opp. at 28), Plaintiff neglects to inform this Court that the State AGs did *not* sue Endo based on *any* of those products. *See State AG Antitrust Litig.*, Dkt. No. 14. Plaintiff similarly wants this Court to believe that the DOJ’s intervention in private antitrust litigation—*In re Generic Pharm. Pricing Antitrust Litig.*, 16-MD-2724 (E.D. Pa.) (“*Generic MDL*”), a multi-district litigation against many pharmaceutical companies coordinated before Judge Rufe—somehow indicates that Endo was engaged in illegal pricing. (Opp. at 28-29; ¶¶ 14, 181-185.) But the DOJ’s motion to intervene addressed only the logistics of discovery, which it sought to stay in part to prevent interference with its investigation, and did not single out *any* company, much less Endo or Par. *See Generic MDL*, Dkt. No. 279. Plaintiff’s references to the government proceedings are, to put it mildly, beside the point.³

Finally, Plaintiff for the first time (in its brief, not in the Amended Complaint) tries to connect the timing of certain Endo product price changes to trade conferences. (Opp. at 10.) But this tactic—which does not find support in Plaintiff’s pleading—further undermines any

² There are no allegations in the State AGs’ complaint relating to Endo, and the allegations as to Par (1) involve a product, doxycycline monohydrate, not at issue here, *compare State AG Antitrust Litig.*, No. 17-CV-03768 (E.D. Pa.), Dkt. No. 14 at ¶¶ 246-267 with AC ¶¶ 98-144; and (2) concern alleged price increases predating Endo’s acquisition of Par, *compare State AG Antitrust Litig.*, No. 17-CV-03768 (E.D. Pa.), Dkt. No. 14 at ¶¶ 246-267 with AC ¶¶ 134.

³ Plaintiff points out that Judge Rufe recently denied a motion to dismiss in the private litigation. (Opp. at 2-3.) That decision has no bearing on whether the pleading *in this case*—where different elements must be pled and heightened PSLRA and Rule 9(b) pleading standards apply—adequately states a claim.

inference of collusion. (*Id.*) Despite 17 alleged conferences and 13 products, Plaintiff can come up with only *four* price increases that occurred some period of time—how much Plaintiff does not specify—after a conference. This may be, at best, indicative of coincidence. It certainly differs from the fact patterns Plaintiff cites for support. *See Perrigo*, 2018 WL 3601229, at *11 (“participation with competitors in trade meetings *immediately preced[ed]* the tandem price hikes”); *Taro*, 2018 WL 4572987, at *2 (“*[r]ight after . . .* meetings, the prices of the generics at issue . . . drastically increased”) (emphases added).

Nothing in Plaintiff’s Amended Complaint remotely amounts to well-pled allegations that Defendants participated in a price-fixing conspiracy concerning the 13 products at issue here, and it certainly does not plead that Defendants misled the market when they failed to disclose this non-existent conduct.

B. Plaintiff’s Alternative Theory Of Falsity Also Fails

Plaintiff also argues that certain statements were supposedly false “independent of whether the price increases and lack of competition were the result of a conspiracy.” (Opp. at 13.) This theory also fails.

1. Defendants’ Statements Regarding Competition Were Accurate

Plaintiff argues that Defendants’ statements that Endo operates in a “highly” or “intensely” competitive industry and faces “intense competition” were false or misleading because Endo “did not compete *on price*.” (*Id.* at 15 (citing ¶ 186(a) (emphasis added).) But this theory erroneously assumes that “competition” can *only* mean *price* competition. What is relevant here is what Endo actually said, not Plaintiff’s conclusory mischaracterizations of it.

The Amended Complaint alleges no facts establishing that competition is based only on price. This alone is sufficient to reject it. *See In re Rockefeller Ctr. Properties, Inc. Sec. Litig.*, 311 F.3d 198, 216 (3d Cir. 2002) (“boilerplate and conclusory allegations will not suffice”). In

any case, nothing in Endo’s statements restricts competition to price competition alone—that is just not what the words say. Such a notion is also undermined by the Amended Complaint itself, which quotes Endo’s disclosures about the many other ways generic manufacturers compete, including: “develop[ing] and launch[ing] new generic products,” “maintain[ing] efficient, high quality manufacturing relationships,” and “focus[ing] on high-value, first-to-file or first-to-market opportunities.” (¶¶ 190, 206, 207.) Endo also explained that “competitive factors” other than price include “product quality . . . , reputation, service and access to scientific and technical information,” and “research and development investments.” (¶ 208.)⁴ Plaintiff cannot maintain a claim by arguing that Endo concealed something its own pleading makes clear was disclosed. *In re Donald J. Trump Casino Sec. Litig.*, 7 F.3d 357, 372 (3d Cir. 1993) (dismissing claims where disclosures “directly address[ed] the substance” of plaintiff’s challenged statements).

Plaintiff’s reliance on *Mylan*, *Taro*, and *Perrigo* further underscores why this theory fails. In *Mylan* and *Taro*, the courts held that statements describing the market as competitive could be misleading because plaintiffs in those cases—unlike here—*adequately pled a price-fixing conspiracy*. See *Mylan*, 2018 WL 1595985, at *7 (“If, as Plaintiffs allege, Mylan was engaged in a variety of anticompetitive practices—often in collusion with Mylan’s competitors—then these statements are misleading in the absence of a disclosure of that anticompetitive conduct.”); *Taro*, 2018 WL 4572987, at *6 (“To the extent that Taro engaged in a price-fixing conspiracy with their competitors, statements that the industry was, for example, ‘intensely competitive[,]’ are ‘misleading in the absence of a disclosure of that anticompetitive conduct.’”) (citing *Mylan*, 2018 WL 1595985, at *7). Similarly, in *Perrigo*, the court found certain statements actionable

⁴ Plaintiff’s conclusory allegation that generic products compete solely on price is thus contradicted by its own Amended Complaint. Moreover, Plaintiff’s theory assumes that, if price is reduced, production can be rapidly increased to accommodate greater demand—ignoring manufacturing and distribution realities.

because the complaint alleged “a direct nexus between the *illegal conduct* and Defendants’ allegedly materially false and misleading statements.” *Perrigo*, 2018 WL 3601229, at *12 (emphasis added). No such facts were pled here. Plaintiff does not cite a single case holding that statements about “competition” were false or misleading due to an independent, non-collusive decision to match rather than undercut a price increase. This theory states no claim.

2. Defendants’ Statements Regarding Income Were Accurate

Plaintiff’s theory regarding the “sources” of Endo’s past income also fails. Plaintiff’s argument is that Defendants allegedly led the market to believe that prior profits were “durable” and “sustainable” when, in actuality, Endo allegedly concealed that price increases were a “secret source of Endo’s revenue that were subject to abrupt termination.” (Opp. at 13 (citing ¶ 186(b)), 17-18.) This, too, is fatally undermined by the Amended Complaint, which refers explicitly to statements to investors that a portion of Endo’s generics growth *was* the result of price increases, and that those price increases were “temporary.” (See ¶ 199 (quoting disclosure that “[Endo is] prudent and opportunistic when [it] take[s] price increases”); ¶ 202 (quoting disclosure that “[t]he controlled substance space has been one where there’s been events that allow for price increases,” and that “they are temporary, but net-net *they contribute to [generics segment] growth*”) (emphasis added).) These disclosures fully undermine Plaintiff’s argument. See *Donald J. Trump Casino*, 7 F.3d at 372.

Plaintiff’s argument that Defendants’ characterization of Endo’s pricing strategies as “prudent” was somehow misleading (Opp. at 19) is also wrong. As explained above, Third Circuit law is clear that, in an oligopolistic market such as those alleged here, raising prices when others do can be a perfectly rational and legal decision by a business acting in its unilateral best interest—and thus prudent. *Chocolate Confectionary*, 801 F.3d at 397. Moreover, the Amended Complaint describes Endo’s rigorous pricing process as involving: compiling data “concerning

pricing, sales, revenue, and profit data on a drug-by-drug basis down to the unit-price level” (§ 42); “prescheduled” discussions of the data among senior executives (§ 43); and a regular review of “generic drugs that presented opportunities for price increases, along with analysis for why those price increases were feasible.” (§ 93(a).) Plaintiff offers no reason why this elaborate process was not “prudent.”

Plaintiff selectively quotes *Mylan*, *Taro*, and *Perrigo* for the proposition that Endo was required to make additional disclosures regarding its sources of income because it put those sources “at issue.” (Opp. at 17, 20.) But once again these cases do not apply here because, in each of them, the disclosure duty arose because plaintiffs had adequately pled a failure to disclose *illegal underlying conduct*. *Mylan*, 2018 WL 1595985, at *6 (“[W]here a company puts at issue the cause of its financial success, it may mislead investors if the company fails to disclose that a material source of its success is the *use of improper or illegal business practices*.”); *Taro*, 2018 WL 4572987, at *7 (holding that failure to disclose a price-fixing conspiracy “called into question whether [Taro’s] ability to secure favorable pricing in the future was durable and due to a legitimate competitive advantage, or whether—*like all illegal arrangements*—it was legally unenforceable and subject to abrupt termination”); *Perrigo*, 2018 WL 3601229, at *12 (statements regarding “pricing pressure” were actionable where the complaint alleged a “direct nexus between the *illegal conduct* and Defendants’ allegedly materially false and misleading statements”) (all emphases added). One fundamental problem here is Plaintiff’s failure to plead this sort of underlying illegal conduct.

3. Defendants’ Statements Regarding Product Pricing Were Accurate

Plaintiff’s reliance on certain statements regarding Endo’s pricing to claim that Endo concealed the extent to which price increases played a role in the growth of its generics business also fails. (Opp. at 20.) As one example, Plaintiff asserts that Mr. De Silva said that Endo had

“not been dependent on pricing.” (*Id.*) But that is *not* what he said. What Mr. De Silva actually said was that Endo’s “business is not dependent on price as a driver of *long-term* growth.” (Ex. 1, Endo 2015 Q3 Earnings Call Transcript, at 11 (emphasis added).) Mr. De Silva further elaborated that “while, historically, the [generics] business did enjoy a certain amount of price . . . growth, now [generics] itself has grown in the midteens organic[ally] in the last 5 years and 2/3 of that growth . . . came from volume and mix.” (*Id.*) In other words, Mr. De Silva’s complete statements (unedited by Plaintiff) disclosed that one-third of the growth in the generics business was attributable to pricing—*nearly the exact percentage of reported generics income that Plaintiff alleges was fraudulently concealed*. (Opp. at 20 (arguing that Endo concealed that “30% of reported generics income” in 2014 and “32% of the Company’s overall generics profits” in 2015 were the result of price increases)). Here again, no claim can be stated where Endo disclosed what Plaintiff contends was concealed. *See Donald J. Trump Casino*, 7 F.3d at 372.

Plaintiff’s reliance on *Taro* and *Perrigo* on this point is again misguided. Those cases turned on the failure to disclose illegal conduct, which is not adequately alleged here. *See, e.g., Taro*, 2018 WL 4572987, at *7. And in *Perrigo*, the court found that defendants’ statement that pricing for generics was “flat to up slightly” was misleading where defendants allegedly failed to disclose illegal “collusive revenue” that comprised over a quarter of the company’s generics segment revenue in 2016. *Perrigo*, 2018 WL 3601229, at *10. Among other things, the failure to plead illegality here distinguishes that reasoning.

4. Numerous Challenged Statements Are Protected As Forward-Looking And Puffery

Plaintiff argues that Defendants took certain statements “out of context” in arguing that they are protected as puffery under the securities laws, citing *Perrigo* for the alleged proposition that “statements regarding competitiveness” are not puffery. (Opp. at 32.) Ironically, however,

Plaintiff takes *Perrigo* out of context, as that case held that certain statements regarding competition were not puffery where, unlike here, the plaintiff adequately pled illegal anticompetitive conduct. *Perrigo*, 2018 WL 3601229, at *12. It does not support Plaintiff's proposed general rule that "statements regarding competitiveness" can never be puffery.

Plaintiff further argues that Endo's statements to the effect that it "*will* maintain [an] opportunistic approach to supply and demand imbalances" and that the "CDC guidelines *will* continue to put pressure on a[n] already soft pain market" do not qualify for the PSLRA's safe harbor for forward-looking statements because they are not "purely forward looking" but rather are "mixed present/future statements." (Opp. at 32 (emphasis added).) As an initial matter, what Plaintiff characterizes as statements of present fact are too vague to render them non-forward-looking. *See Institutional Inv'rs Grp. v. Avaya*, 564 F.3d 242, 256 (3d Cir. 2009) (vague phrases like "on track" do "not transform the statements, or any part of them, into non-forward-looking assertions outside of the Safe Harbor"). In any case, Plaintiff also fails to allege with particularity that the so-called "historical fact[s]" embedded in these statements are false—*i.e.* that Endo did not employ such an "opportunistic approach" or that the CDC guidelines did not put pressure on the pain market. (Opp. at 32-33) These statements plainly look to the future, and are fully protected by the safe harbor. Plaintiff offers no contrary authority.

II. PLAINTIFF FAILS TO ALLEGE A STRONG INFERENCE OF SCIENTER

Plaintiff does not come close to establishing the required "strong inference" of scienter. It points to no facts establishing that any Defendant intentionally misled investors or ignored a risk of misleading investors that was "so obvious" as to represent "an extreme departure from the standards of ordinary care." *In re Radian Sec. Litig.*, 612 F. Supp. 2d 594, 613-14 (E.D. Pa. 2009). This is an independent basis for dismissal. Even if the Court finds that Plaintiff has adequately pled the existence of illegal price-fixing—which it has not—the Court should still

dismiss the claims, as other courts have done in this context, because nothing in the Amended Complaint remotely suggests that any Defendant acted with scienter. *See Utesch*, 316 F. Supp. 3d at 907 (dismissing on scienter grounds); *Impax*, 2018 WL 4616291 at *4 (same). Plaintiff's allegations are no stronger than the allegations those courts found lacking.

A. Defendants' Active Participation In Pricing Suggests Only That Defendants Actively Participated In Pricing

Plaintiff devotes considerable effort to the unremarkable assertion that Endo's senior executives were focused on Endo's pricing. (Opp. at 34-39; ¶¶ 36, 89-94, 222-29.) Indeed, even if allegations from Plaintiff's CWs—flawed as they are (*see* Def. Br. at 19-20)—are accepted at face value, they merely support the notion that Messrs. Campanelli, De Silva, and Upadhyay were closely involved in pricing.⁵ This is far from enough to establish scienter.⁶

Plaintiff never explains why it is surprising or inappropriate for senior executives to be involved in pricing decisions or how this distinguishes Endo from any other company. Nor does Plaintiff show that any Defendants were aware that Endo's prices were the result of alleged price-fixing activity or somehow "unsustainable" (*see, e.g.*, Opp. at 36). Without such facts, Plaintiff simply has not raised any inference of scienter. This is the conclusion in *Utesch*:

It is one thing to say that . . . [senior executives] were aware of the Generic Drugs' price increases. It is another to infer that, due to these price increases [the senior executives] must have known the reason for the increases was due to a price-fixing conspiracy with other major pharmaceutical companies.

316 F. Supp. 3d at 906. The same rationale applies here. Under Third Circuit law, absent particularized allegations that executives knew (or recklessly ignored) information showing the

⁵ The CWs are inadequately pled for the reasons set forth in Defendants' opening brief—and, despite Plaintiff's insinuations (Opp. at 44-46), there is no allegation that any CW actually spoke with any individual Defendant. This alone disqualifies them as a basis for inferring scienter. (Def. Br. at 19-20 (citing cases).)

⁶ Defendants urge the Court to review the actual allegations attributed to the CWs. (¶¶ 89-94.) None says anything at all about any Defendant's intent or about any alleged unlawful pricing.

existence of price-fixing (not merely information about their business), mere allegations of hands-on management will not support scienter. *See, e.g., Rahman v. Kid Brands, Inc.*, 736 F.3d 237, 246–47 (3d Cir. 2013) (adopting proposition that “corporate management’s general awareness of the day-to-day workings of the company’s business does not establish scienter—at least absent some additional allegation of specific information conveyed to management and related to fraud.”) (quotation omitted)); *accord Impax*, 2018 WL 4616291 at *4 (“representations regarding Defendants’ willingness to monitor the market, maximize product opportunities, and exploit positive pricing” did not support inference of scienter in connection with alleged price-fixing).

Scienter also is not established by Plaintiff’s bare assertion that the pricing information to which Defendants had access “contradicted their statements that denied or minimized that Endo made or profited from price hikes.” (Opp. at 35.) Such conclusory allegations fail to support a claim. *See Winer Family Tr. v. Queen*, 503 F.3d 319, 332 (3d Cir. 2007) (“[Plaintiff] failed to adequately plead scienter by failing to link the declarant of the challenged statement with facts that might contradict his statement.”). Factual allegations are required that “detail specific contemporaneous data or information known to the defendants that was inconsistent with the representation[s] in question.” *Hart v. Internet Wire, Inc.*, 145 F. Supp. 2d 360, 368 (S.D.N.Y. 2001) (citation omitted). In any event, Plaintiff’s own allegations again undercut this theory. For example, the Amended Complaint quotes Mr. De Silva as expressly telling investors exactly what Plaintiff argues was concealed: that Endo is “opportunistic when we take price increases” and actively looking for “opportunities to take price” (§ 199), and that even though “many” price increases “don’t last very long, and they are temporary,” that “net-net they contribute to Qualitest growth” (§ 202). This, too, undermines any inference of scienter. *See Gillis v. QRX Pharma*

Ltd., 197 F. Supp. 3d 557, 602 (S.D.N.Y. 2016) (accurate disclosures undermined an inference of scienter).

Plaintiff again seeks refuge in *Mylan*, *Perrigo*, and *Taro*. None is availing. In *Perrigo*, plaintiff's scienter allegations were buttressed by the fact that DOJ "raided Perrigo's offices as part of a criminal price-fixing probe." *Perrigo*, 2018 WL 3601229, at *21. That did not happen here. *Mylan*, of course, involved specific factual allegations that company executives had actually entered into a price-fixing agreement, supporting the pleading inference that "individual Defendants either consciously participated in price-fixing, or were at least reckless in ignoring information indicating that price-fixing was occurring." *Mylan*, 2018 WL 1595985, at *17. No similar allegation is made here. And *Taro*, following *Mylan*, was likewise premised "upon [plaintiff's] well-supported allegations regarding the price-fixing conspiracy[.]" *Taro*, 2018 WL 4572987, at *8. Plaintiff exaggerates and distorts the applicability of those cases here. They do not support any inference of scienter.

B. Defendants' Focus On The Generics Market Also Does Not Give Rise To An Inference Of Fraud

Plaintiff asserts that Defendants must have had scienter because the generics markets were "particularly important to Endo, and Defendants repeatedly spoke about it with investors." (Opp. at 40.) To the extent that Plaintiff is trying to make out a "core operations" theory of scienter, it does not apply here. In very limited circumstances, that theory presumes executives' scienter for certain "core" aspects of their companies. *Utesch*, 316 F. Supp. 3d at 905-06. But for it to apply, it is not enough that the business area in question be merely "important": rather, Plaintiff must plead facts establishing that Defendants, by virtue of their positions, were consciously involved in the fraud and that the product at issue was responsible for "*nearly all of a company's business.*" See *Tyler v. Liz Claiborne, Inc.*, 814 F. Supp. 2d 323, 343 (S.D.N.Y.

2011) (emphasis added); *see also In re Am. Bus. Fin. Servs., Inc. Sec. Litig.*, 413 F. Supp. 2d 378, 403 (E.D. Pa. 2005) (“core operations” theory inapplicable absent “facts that the individual defendants’ positions were such that they were consciously involved in a scheme to defraud investors”). Plaintiff pleads neither here. The Amended Complaint concedes that the products in question generated *less than half* of the income of just *one* of Endo’s divisions (§§ 6, 10), and there are no facts establishing any “conscious involvement” in a fraud by any Defendant. *See Impax*, 2018 WL at 4616291 at *4 (no scienter where no facts established that “Defendants actually orchestrated or knew of the alleged collusive activity”).

Equally deficient is Plaintiff’s contention that Defendants’ “confident, unhedged” answers in the face of “repeated questions about pricing by analysts” support scienter. (*See Opp.* at 41 (citing *Avaya*, 564 F.3d at 270; *Perrigo*, 2018 WL 3601229, at *21).) The Amended Complaint alleges no such thing—citing just *three* analyst questions about pricing (§§ 199, 202, 256)—and in each instance Mr. De Silva *disclosed precisely what Plaintiff contends was concealed* by acknowledging that Endo *does* raise prices on generic products when the timing is right, even when the price increases are short-lived. (*Id.*) Plaintiff cites no case law in which accurately answering three analyst questions was somehow indicative of scienter. The *Utesch* court rejected scienter where defendants answered questions about pricing and competition on *five* investor calls, as this did not raise an inference of “knowledge that the prices were the result of price-fixing.” 316 F. Supp. 3d at 906. The same result is appropriate here.

C. Plaintiff’s Motive Allegations Are Insufficient And Implausible

Plaintiff does not dispute that, in the Third Circuit, motive alone cannot establish scienter. (Def. Br. at 17-18 (citing cases).) Plaintiff nevertheless persists in trying to establish Defendants’ motive based on roundly rejected and contradictory theories.

Plaintiff argues that the lack of insider sales does not “negate[]” an inference of motive (Opp. at 43), but its own case law holds otherwise. *See Perrigo*, 2018 WL 3601229, at *17 (“The fact that only two of the Individual Defendants are alleged to have made insider sales undermines Plaintiff’s claim that there was a motive to commit fraud.”). This is consistent with Third Circuit law, which holds that a lack of stock sales “raise[s] doubt” about defendants’ scienter. *In re Advanta Sec. Litig.*, 180 F.3d 525, 540 (3d Cir. 1999), *abrogated on other grounds by Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308 (2007); *accord In re PDI Sec. Litig.*, 02-Civ-0211 (GEB), 2006 WL 3350461, at *16 (D.N.J. Nov. 16, 2016) (lack of insider stock sales “effaces” an inference of scienter). Unable to allege insider stock sales, Plaintiff has not identified any “concrete and personal benefit to the individual defendants” that could establish motive. (Def. Br. at 20-21 (quoting *GSC Partners CDO Fund v. Washington*, 368 F.3d 228, 237 (3d Cir. 2004).))

Plaintiff is thus left to argue an utterly implausible motive theory. Plaintiff contends that Defendants were motivated to fraudulently inflate Endo’s stock price in an “unsustainable” scheme to acquire other companies at prices inflated by virtue of their participation in the same unsustainable scheme. This generic theory is insufficient on its face to support an inference of scienter. *See Utesch*, 316 F. Supp. 3d. at 905 (no inference of scienter from inflating stock price to fund a “growth-by-acquisition strategy”).⁷ That this theory is without merit is underscored by Plaintiff’s new argument that Defendants must have actually believed the price increases “would

⁷ The cases Plaintiff cites (Opp. at 42-43) do not find scienter on the basis of such allegations alone. *See In re Ravisent Techs., Inc.*, 2004 WL 1563024, at *8-9 (E.D. Pa. July 13, 2004) (plaintiffs alleged, in addition to motive, facts that defendants’ failure to comply with stated internal revenue policies resulted in “grossly overstat[ing]” the company’s financial statements); *Rothman v. Gregor*, 220 F.3d 81, 92 (2d Cir. 2000) (plaintiffs alleged, in addition to motive, facts raising a “strong inference of recklessness” due to the company’s unexplained refusal to expense royalty advances).

successfully continue” (Opp. at 43)—despite arguing throughout the first 40 pages of its brief that this pricing practice was *unsustainable*. (*Id.* at 1, 7, 22, 36.) Plaintiff cannot have it both ways. This is not, as Plaintiff suggests, a “factual” issue precluding dismissal. (*Id.* at 43.) Courts routinely reject such internally inconsistent and generic theories at the pleading stage. *See Kalnit v. Eichler*, 264 F.3d 131, 140-41 (2d Cir. 2001) (rejecting motive allegations that were “not only conclusory and speculative, but nonsensical as well”). In any event, Plaintiff cannot offer brand new theories in an opposition brief. *See Burton v. Ken-Crest Servs., Inc.*, 127 F. Supp. 2d 673, 674 n.2 (E.D. Pa. 2001) (rejecting Plaintiff’s attempt to assert a “new theory” that was “contradicted by the organization and substance of [its] complaint”); *see also Com. of Pa. ex rel. Zimmerman v. PepsiCo, Inc.*, 836 F.2d 173, 181 (3d Cir. 1988) (“[I]t is axiomatic that the complaint may not be amended by the briefs in opposition to a motion to dismiss.”) (citation omitted). Plaintiff’s 180-degree reversal on a fundamental allegation speaks volumes about the merit of its case generally.

D. Plaintiff’s Additional Attempts to Bolster Its Scienter Allegations Fail

Plaintiff’s brief also pushes a number of throwaway generic scienter theories. None has merit. As one court explained in similar circumstances, “[f]our cubic zirconias will never add up to one real diamond and neither will four generic motives add up to one or more specific motives.” *In re Carter-Wallace, Inc. Secs. Litig.*, No. 94-civ-5704, 1999 WL 1029713, at *5 (S.D.N.Y. Nov. 9, 1999).

Plaintiff cites the magnitude of an alleged fraud (Opp. at 41-42), but the law is clear that “the size of an alleged fraud alone does not create an inference of scienter,” especially where, as here, there are no facts establishing an underlying fraud. *See Plumbers & Steamfitters Local 773 Pension Fund v. Canadian Imperial Bank of Commerce*, 694 F. Supp. 2d 287, 302 (S.D.N.Y. 2010) (citing *In re PXRE Grp., Ltd., Sec. Litig.*, 600 F. Supp. 2d 510, 545 (S.D.N.Y. 2009)); *see*

also *In re Stonepath Grp., Inc. Sec. Litig.*, 397 F. Supp. 2d 575, 587-88 (E.D. Pa. 2005) (“magnitude” of an alleged fraud “does not establish recklessness” without more).

Plaintiff cites the resignations of Messrs. De Silva and Upadhyay, but is unable to link those resignations to any of its allegations and so they are irrelevant—as Plaintiff’s own case law holds. *See Perrigo*, 2018 WL 3601229, at *22 (“the Court finds little if any probative value in the fact of [executive’s] resignation” despite Plaintiff’s attempt to create a temporal link between the resignation and allege pricing scheme); *see also In re Hertz Glob. Holdings Inc.*, 905 F.3d 106, 118 (3d Cir. 2018) (holding resignations did not support scienter where they were not linked to the alleged fraud).

Plaintiff also relies on the DOJ investigation and the State AGs’ lawsuit (Opp. at 43-44), but they do not raise an inference of scienter in any way. As discussed above, Plaintiff substantially misstates the relevance of those matters to this case. Plaintiff must do more than point to the fact that the government is investigating generic pharmaceutical companies, since “government investigations cannot bolster allegations of scienter that do not exist.” *Mylan*, 2018 WL 1595985, at *17 (citation omitted); *see also Utesch*, 316 F. Supp. 3d at 903-04 (finding “unpersuasive” for scienter governmental inquiries into defendant’s purported antitrust violations). Without other well-pled allegations of scienter—and here there are none—“the mere occurrence of [an] investigation is equally consistent with Defendants’ innocence” as it is with misconduct. *Superior Offshore Int’l, Inc. v. Bristow Grp. Inc.*, 738 F. Supp. 2d 505, 517 (D. Del. 2010), *aff’d* 490 F. App’x 492 (3d Cir. 2012).

E. The More Compelling Inference Is That There Was No Fraud

The Supreme Court requires courts to consider alternative, nonfraudulent inferences and to grant motions to dismiss unless the inference of fraud is “at least as compelling.” *Tellabs*, 551 U.S. at 314. Here, Plaintiff has failed to rebut a nonfraudulent inference, entirely consistent with

Third Circuit antitrust law: that Endo and its executives, through careful review and study of pricing in the generics industry and “cognizant of the small number of pharmaceutical companies” in each market, raised the prices of its products in order to generate revenue and increase the value of the business for the benefit of shareholders like Plaintiff. *Utesch*, 316 F. Supp. 3d at 907 (finding more compelling inference that defendants raised prices independently due to small number of competitors, not knowledge of price-fixing). With the benefit of hindsight, Plaintiff disagrees with the decisions Defendants made to advance that goal. Such disagreements do not support an inference of fraud. See *Winer Family Tr.*, 503 F.3d at 331-32 (rejecting attempt to plead fraud by hindsight); *Boca Raton Firefighters & Police Pens. Fund v. Bahash*, 506 F. App’x 32, 36 (2d Cir. 2012) (“Section 10(b) . . . does not reach mere instances of corporate mismanagement.”) (citation omitted).

Conclusion

For the reasons set forth above and in Defendants’ brief in support of their motion to dismiss, the Amended Complaint fails to state a claim as a matter of law. It should be dismissed with prejudice.

Dated: November 9, 2018

Respectfully submitted,

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EXHIBIT 1

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FQ3 2015 Earnings Call Transcripts

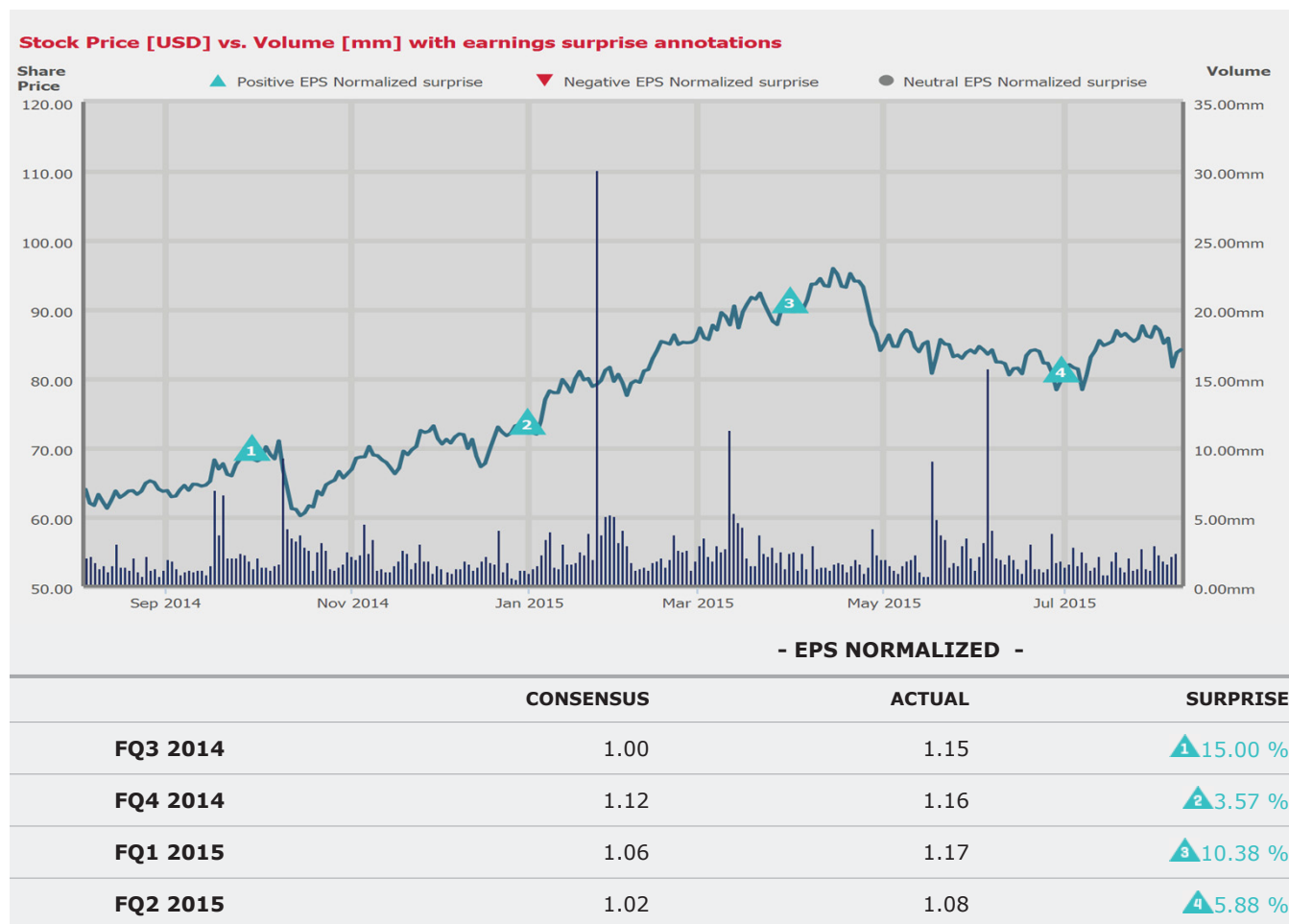
Thursday, November 05, 2015 1:30 PM GMT

S&P Capital IQ Estimates

| | -FQ3 2015- | | | -FQ4 2015- | -FY 2015- | -FY 2016- |
|-----------------------|------------|--------|----------|------------|-----------|-----------|
| | CONSENSUS | ACTUAL | SURPRISE | CONSENSUS | CONSENSUS | CONSENSUS |
| EPS Normalized | 1.00 | 1.02 | ▲ 2.00 | 1.31 | 4.56 | 5.99 |
| Revenue (mm) | 737.65 | 745.73 | ▲ 1.10 | 1077.66 | 3268.87 | 4748.45 |

Currency: USD

Consensus as of Oct-28-2015 7:01 AM GMT



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Presentation

Operator

Good day, ladies and gentlemen, and welcome to today's Endo International Third Quarter Earnings Conference Call. [Operator Instructions] As a reminder, this conference is being recorded. I would like to introduce your host for today's conference, Ms. Keri Mattox. Ma'am, you may begin.

Keri P. Mattox

Former Senior Vice President of Investor Relations & Corporate Affairs

Good morning, and thank you for joining us to discuss our third quarter 2015 financial results. With me on today's call are Rajiv De Silva, President and CEO of Endo; Suky Upadhyay, Chief Financial Officer; Paul Campanelli, President of Par Pharmaceuticals; and Brian Lortie, President of U.S. Branded Pharmaceuticals. We have prepared a slide presentation to accompany today's webcast, and that presentation is posted online in the Investors section at www.endo.com.

I would like to remind you that any forward-looking statements by management are covered under the Private Securities Litigation Reform Act of 1995 and Canadian Securities Litigation Act and are subject to the changes, risks and uncertainties described in today's press release and in our U.S. and Canadian securities filings.

In addition, during the course of this call, we may refer to non-GAAP financial measures that are not prepared in accordance with accounting principles generally accepted in the United States and that may be different from non-GAAP financial measures used by other companies. Investors are encouraged to review Endo's current report on Form 8-K furnished with the SEC today for Endo's reasons for including those non-GAAP financial measures in today's earnings announcement. The reconciliation of non-GAAP financial measures to the most directly comparable GAAP financial measures is contained in our earnings press release issued prior to today's call.

With that, I would now like to turn the call over to Rajiv.

Rajiv Kanishka Liyanaarchchie De Silva

Former Chief Executive Officer, President and Director

Thank you, Keri, and good morning, everyone, and thank you for joining us for today's call. I hope that you have all had a chance to review the company's earnings press release that we issued earlier this morning. Let me now turn to our third quarter earnings presentation.

On Slide 2, you will see our agenda for today's call. We will start with an overview of Endo's transformation since the beginning of 2013 and how we believe we have differentiated ourselves within the specialty pharmaceutical landscape. We will then review some of our recent accomplishments, and I will follow that with the highlights of our third quarter 2015 financial results, walking through our U.S. Branded, U.S. Generics and international businesses. We will then turn to our full year 2015 outlook and financial guidance as well as our projected 2016 financial profile. After our prepared remarks, we look forward to taking your questions.

Moving on to Slide 4. Shortly after I joined the company in early 2013, we mapped out a strategic direction that we felt best positioned Endo for transformative growth and to achieve our goal of improving lives while creating value. We aspire to become a leading global specialty pharmaceutical company and are focused on areas where we believe we can create value. Our core businesses are U.S. Branded Pharmaceuticals, U.S. Generics and International Pharmaceuticals.

At Endo, we aim to create value through our differentiated operating model. With our nimble decentralized structure and rational allocation of capital, we believe we are better owners of assets. Ultimately, this model is enabling us to achieve sustainable growth through organic expansion, strategic M&A and a derisked R&D pipeline.

On Slide 5, you will see the core tenets of the Endo operating model and what we believe differentiates us from other companies in our industry. It is important to note that while we continue to see M&A as an important component of building and growing our business in the future, we have already diversified and expanded our product portfolio and R&D pipeline to support double-digit organic growth. Finally, we're a streamlined, diversified and compliant organization that operates within the rigorous controls of our industry.

Moving to Slide 6. You will see the key components of Endo's strategic transformation. First, we have optimized and refocused the Endo business for sustainable growth. Our efforts have enabled us to successfully rightsize our cost base and upgrade our management talent. We have divested the noncore assets of HealthTronics and AMS Men's Health to sharpen the strategic focus on pharmaceuticals and our base business. We completed bolt-on acquisitions like Boca, DAVA and Sumavel DosePro that added near-term critical mass at key points in our corporate evolution. Finally, we expanded the R&D pipeline with the addition of AVEED, creating a new branded growth opportunity.

Now moving beyond our base business. We have created new long-term growth platforms for Endo. The Auxilium transaction, which closed earlier this year, was an important step in rebuilding our U.S. Branded business and brought XIAFLEX, TESTOPEL and other innovative products into our portfolio. That transaction also helped revitalize the R&D pipeline, with the addition of multiple XIAFLEX programs across a range of potential therapeutic and aesthetic indications. We established our international platform to further diversify our revenue base. The acquisitions of Somar in Mexico, Litha in South Africa and a portfolio of products from Aspen group strategically augment Litha business, established emerging market beachheads for us. These international businesses also facilitate further international expansion in these regions.

Finally, BELBUCA, which was just approved by the FDA, firmly positions Endo for growth again in the pain market. We are tapping the full breadth and depth of Endo's expertise in this area, as we prepare for commercial launch early next year. In short, we are positioned for successful execution of this opportunity. We have also taken transformational steps towards leadership in the global specialty pharmaceutical arena. The transformational acquisitions we've successfully pursued, namely Paladin and, more recently, Par, have enabled us to improve our corporate structure and firmly position the company for long-term organic growth.

Additionally, we have transformed our pipeline. As I mentioned a few moments ago, XIAFLEX brings a range of new programs to our R&D efforts from indications with severely underserved patient populations and few treatment options to broader aesthetic indications with significant market potential. Further, the addition of Par brings an industry-leading specialty pipeline of more than 200 products to our U.S. Generics business. Approximately 2/3 of Par's R&D programs are in alternative dosages and approximately half of Paragraph IV first-to-file or first-to-market opportunities. This pipeline has been consistently producing higher barrier-to-entry products with fewer competitors and higher gross margins, and we expect it to continue to do so, driving double-digit growth for Endo over the near and midterm.

Next on Slide 7, you will see how the Endo transformation has resulted in a strategic shift in our revenues in recent years. Through a mix of portfolio diversification, product life-cycle management, organic growth acceleration and accretive M&A, the Endo of 2015 is a vastly different company than the Endo of 2012. For example, in 2012, 72% of Endo's revenues were comprised of noncore businesses such as AMS and HealthTronics and now legacy branded products like LIDODERM. In 2015, legacy branded products are projected to be only approximately 17% of our overall revenues, and HealthTronics and most of AMS have been divested. In fact, today, no Endo product makes up more than 6% of overall revenues. We have truly diversified.

We are also building out portions of our business that we believe will create value well into the future. Our U.S. Branded portfolio has expanded. We have enhanced our generics business and have added an international business.

Moving to Slide 8. You will see how this diversification and company growth has impacted our earnings per share, essentially turning the company's EPS around from the impact of the decline of legacy products and noncore businesses.

Moving to Slide 9, and heading into 2016, we believe our recent milestones make Endo fundamentally stronger than ever for several reasons. We are positioned for growth, which means that we are projecting a double-digit organic growth rate over a planning horizon and are increasing our operating margins. We are also progressing our tax strategy. We have a powerful platform for future M&A. Post Par, we have enhanced corporate profile, scope, size and manufacturing capabilities. Also with robust underlying cash flow and adjusted EBITDA in 2016, we anticipate rapidly delevering back to a 3x to 4x net debt-to-EBITDA ratio by mid-2016. And we have built an expanded diversified portfolio. As I mentioned just a few minutes ago, we have strategically grown our product portfolio and R&D pipeline across all 3 of our business segments.

So moving to Slide 11. We continue to make good progress in addressing the near-term strategic priorities that we believe will support our objective of becoming a leading global specialty pharmaceutical company. First, we are further enhancing our operational focus in order to help drive organic growth. In our U.S. Branded business, we secured FDA approval for BELBUCA, continued to drive growth for XIAFLEX and supported OPANA ER, working to defend our IP estate and toward a potential label expansion.

In U.S. Generics, we closed the acquisition of Par, achieving critical mass for this business. Within international, we closed the Aspen portfolio acquisition for the Litha growth, which is now refocused on pharmaceuticals. Second, we continue to sharpen our R&D focus on near-term opportunities. On the late-stage development front for XIAFLEX, we have made good progress on our additional studies for the treatment of cellulite and adhesive capsulitis. We expect to hold confirmatory meetings with the FDA by the end of this year, and will initiate these 2 studies shortly thereafter.

Also, I'm pleased to share an exciting update regarding the earlier stated XIAFLEX pipeline. We have opted into 2 new potential indications recently, lateral hip fat and plantar fibromatosis. I will talk more about these in detail in a few minutes. Third, we are focused on deploying capital to accretive value-creating opportunities such as the Par and Aspen portfolio acquisitions that I have already mentioned. Fourth, we remain focused on delivering strong and sustainable financial performance. We have a solid third quarter and are maintaining our guidance for full year 2015 revenues and adjusted diluted earnings per share from continuing operations. We are also affirming our 2016 guidance for adjusted diluted earnings per share.

Moving on to Slide 13. You will see that we are reporting \$746 million in revenues for the third quarter, up 14% versus the prior year and \$1.02 in adjusted diluted earnings per share from continuing operations. Suky will provide more details about our third quarter results in just a few minutes.

Next I'd like to discuss the revitalization of our U.S. Branded Pharmaceuticals business in more detail. On Slide 15, you will see our total growth year-to-date is 25% and that, while muted by third quarter underperformance versus expectations in some areas of the portfolio such as STENDRA, we continue to see underlying sales growth for the 9 months ended September 30, 2015, compared to the same period in 2014. This underlying growth rate includes Auxilium results on a pro forma basis and includes only same-store sales for other 2014 acquisitions. For comparison purposes, we exclude the sales of LIDODERM and royalties received from Actavis for its generics lidocaine patch from this calculation.

One of our expected key long-term growth drivers, XIAFLEX, continues to perform in line with our expectations. I will provide a more in-depth review of XIAFLEX shortly. We continue our comprehensive efforts to protect the OPANA ER franchise, including the promotion and development of the product as well as the vigorous assertion of its intellectual property. The positive ruling in the Paragraph IV patent infringement trial held earlier this year in the Southern District of New York strengthens our IP portfolio and should remove one of the generic competitors from the market. We also have ongoing litigation we initiated in late 2014 in the District of Delaware with respect to newly issued patents covering the product. In parallel, and following our discussion with the FDA earlier this year, we expect to submit a supplemental request for labeling that would potentially add abuse-deterrent formulation claims. We expect to file that request in late 2015 or early 2016.

We believe our branded pricing strategy is rational and appropriate and that volume continues to be the primary driver of our growth in our U.S. Branded business. While there's a range of wide price increases

across our portfolio annually, we estimate that our effective annual price increases are approximately 5% for this business after discounts and rebates.

Moving on, as you all know, there have been many questions about the industry's use of specialty pharmacies recently. Let me reiterate that we utilize specialty pharmacies for our complex specialty and physician-administered products and that specialty pharmacies account for only approximately 3% of total Endo revenues. Additionally, and importantly, Endo does not have any ownership interest in consolidated financial results of or have any affiliations with any specialty pharmacy. The specialty pharmacies we utilize are independent or are part of other independent companies. We recognize revenues when Endo ships to a specialty pharmacy and it takes title of the product, just as we would with any other distributor.

With that, let's move on and talk about some of the development initiatives in U.S. Branded -- in the U.S. Branded segment that we feel position us strongly for future growth. Moving to Slide 16. We are extremely pleased about the recent FDA approval of BELBUCA, the first and only buprenorphine buccal patch for chronic pain. With more than 100 million adults in the U.S. suffering from chronic pain and more than 130 million opioid prescriptions each year, this is a sizable \$13 billion market. We believe that BELBUCA provides a new and differentiated Schedule III product for these patients, one that combines the proven efficacy and established safety profile of buprenorphine with a novel delivery system that adds convenience and flexibility. With 7 approved dosage strengths, BELBUCA gives physicians the ability to individualize titration and treatment. We are planning for an early 2016 launch of BELBUCA and will expand our pain field force and infrastructure to support our commercial efforts. We are currently building our product inventory to support that commercial launch.

Moving to Slide 17. Given the recent approval of BELBUCA and our launch plans, we are undertaking a portfolio optimization across our branded business. Resources will be reallocated to support key growth drivers like XIAFLEX, BELBUCA and others highlighted here in the green box. And as a result, we expect to deprioritize select products shown here in gray.

On Slide 18, let me provide more detail. First, we will increase our support of our primary growth driver products. As I just mentioned, for BELBUCA, we will more than double the pain field force this year in preparation for an early 2016 launch. For XIAFLEX, we are rolling out a patient engagement campaign to build awareness and we are continuing our efforts to increase our active injector base. For TRT, we are focusing our efforts on our portfolio of differentiated long-acting products, AVEED and TESTOPEL. We see these products as a growth opportunity within the TRT market and for Endo, and we are also continuing our active support for other growth drivers such as SUPPRELIN LA and Voltaren Gel. We do expect that other products in our portfolio will be deprioritized. First, STENDRA. While our relaunch has stabilized STENDRA in a crowded and noisy ED market, it has not yielded inflection point nor accelerated growth that we were looking towards. Second, the overall TRT market continues to decline at a rate of nearly 10% over the last 12 months, and topical gel products like Testim and FORTESTA have gone generic and become commoditized. And though early in its launch phase, even the novel delivery of Natesto has yet to gain significant traction within the legacy gel space.

The accounting impact of the underperformance of these deprioritized products and the strategic reprioritization is an impairment charge taken in Q3, and Suky will talk more about this in detail in a few minutes.

Moving to Slide 19. Let's talk about how one of our key growth drivers, XIAFLEX, performed in the third quarter. While there was some seasonality in Q3, XIAFLEX performed in line with our internal expectations. Growth in demand vials remained strong and with approximately 13,900 vials of XIAFLEX shipped during third quarter 2015. That is an increase of 21% compared to the same period last year. Most of that growth is attributable to the launch in Peyronie's disease, which accounted for approximately 7,500 demand vials, an increase of 33% over the third quarter of 2014. We now have more than 2,300 physicians certified and 11,600 ED patients have been treated with XIAFLEX to date, a key metric that we believe illustrates the strong utilization trends of XIAFLEX with an average vial per patient which is currently at about 4.5 vials.

Demand growth in Dupuytren's contracture was attractive during the quarter as well and increased 14% over the third quarter of 2014 to approximately 6,400 demand vials in third quarter 2015. This continued growth is especially encouraging given that XIAFLEX for DC was launched 5 years ago. We have also

highlighted our average number of XIAFLEX vials for DC patients, which is currently at about 1.2 vials. This supports early indications of solid reduction for multi-cord use following that label expansion late last year.

Finally, to support and grow XIAFLEX demand in Q4 and beyond, we are working to expand the current active injector base and are launching a targeted DTC campaign aimed at building broader patient awareness of the disease and the available treatment options.

On Slide 20, you can see the strong year-to-date growth in both Peyronie's disease and Dupuytren's contracture. We are pleased by XIAFLEX performance this year and are encouraged as we move into the fourth quarter and beyond.

Next, we remain committed to growing our U.S. Branded business organically, and our expanding R&D pipeline is key to those efforts. On Slide 21, you will see a broad overview of our R&D projects including several new XIAFLEX programs in both disease or injury-related conditions as well as aesthetic indications. We are advancing a Phase II program in Dupuytren's nodules to potentially further expand our treatment capabilities in that indication, and along with our partner BioSpecifics, we are moving forward with several exciting additional early stage opportunities. In fact, we have just formally opted into 2 new indications: lateral hip fat and plantar fibromatosis, which is a benign but painful nodule that grows in the bottom of the foot and can require surgery for removal.

Now let's talk about the transformation of our generics business. Moving to Slide 23. U.S. Generics continued to deliver impressive results in the third quarter with sales of \$368 million. That contributes to year-to-date total growth of 32% versus the prior year. Our year-to-date 2015 results primarily benefit from organic growth, including new product launches and a number of value-creating acquisitions. While growth from the strategic initiatives is attractive, more impressive is the robust 24% year-to-date underlying growth rate in our U.S. Generics business. Underlying growth, which excludes Par, was driven by volume, and essentially now that we have closed the acquisition of Par, we are confident that we can deliver double-digit revenue growth for this business for the full year.

Our view on the pricing environment within generics remains consistent. We believe that commodity products face pressure while specialty products face some strategic pricing opportunities depending on market conditions. Given the focus of our U.S. Generics business and our ongoing portfolio and pipeline optimization process, which will continue to prioritize differentiated products, we believe this business can continue to outperform the broader market.

Organic growth drivers are important for each of our businesses, and in generics, we expect to launch 5 to 7 new generic products in Q4 and remain on track to file 20 to 25 ANDAs in 2015.

Moving on to Slide 24. It is important to note that our U.S. Generics business continues to be an extremely attractive and effective growth driver for Endo, with the acquisition of Par. Completed in the third quarter, we believe that we have created significant value and have achieved critical mass in our U.S. Generics business units.

Moving to Slide 25. The addition of Par's generic pipeline to Endo provides compelling opportunities in both the near and long term. In 2016 and 2017, we expect approximately 50 total launches with \$16 billion of current market value according to IMS sales data. Of those launches, we expect 8 to be first-to-file opportunities with \$8 billion of branded market value. In 2018 and 2019, we expect approximately 70 total launches with \$13 billion of market value, of which, we expect 12 to be first-to-file opportunities with \$4 billion of branded market value. That represents a collective potential of approximately 120 launches with more than \$29 billion of current market value and is an industry-leading set of near-term growth drivers. And we have opportunities to increase the contribution from the pipeline, particularly in the 2018 and 2019 time frame. Par's total pipeline includes launches through 2019 as well as products currently assumed to launch after 2019. The pipeline includes 47 products that could potentially be first-to-file or first-to-market and represent a total opportunity of \$42 billion in market value.

On Slide 26, you will see the anticipated product launch information for 2015 to 2019 that we have previously shared with you. We believe this cascade of first-to-file and differentiated product launches support our growth projections moving forward.

Next, let's talk briefly about building our international platform. Moving to Slide 28. While 2015 remains a transition year, our International Pharmaceutical business is performing well and meeting our expectations. The base Paladin business delivered a solid performance supported by the recent launches of Iclusig and Monurol. Somar, our Mexican business, is delivering results in line with expectations. And we continue to sharpen our focus on core pharmaceuticals for the Litha growth in South Africa. We have completed the acquisition of a diverse product portfolio from Aspen and our previously announced divestiture of Litha's device, vaccine and additional noncore product lines is expected to close by early 2016 subject to regulatory approval.

Finally, our international strategic portfolio optimization continues. This process should help us complete the transition for these businesses and deliver the underlying double-digit organic growth that we aspired to in these attractive emerging markets.

So with that, let me turn the call over to Suky to provide some more details of our financial performance for the quarter. Suky?

Suketu P. Upadhyay

Former Chief Financial Officer and Executive Vice President

Thanks, Rajiv, and good morning to those joining us for today's presentation. We are pleased with the solid performance that Endo delivered in the third quarter of 2015.

Starting with Slide 30, I'll walk you through some of the financial details for the third quarter. Revenues increased 14% versus the third quarter of 2014, and year-to-date revenues have increased 28% versus the same period in 2014. For our U.S. Branded business, the acquisition of Auxilium was the primary growth driver -- driver of growth. Our U.S. generics business continued to deliver strong base business growth. For international, a stronger dollar was a key contributing factor to the year-over-year quarterly performance. On an underlying basis, organic year-to-date revenue growth was approximately 4%. Clarity underlying growth for Endo includes Auxilium results on a pro forma basis and only includes 2014 acquisitions on a same-store sales basis, and we exclude all sales and royalties related to LIDODERM for comparison purposes. For the full year 2015, we expect that our underlying growth rate will approximate our longer-term aspirations for sustainable high single-digit to low double-digit organic growth, and the recent closing of Par accelerates our growth profile.

Moving to Slide 31. We continue to expand our adjusted gross margin with 63.5% in the quarter, in line with our overall full year guidance. And our adjusted operating expenses were approximately 21% of revenues, also in line with our expectations. We've been very efficient in capturing synergies from the Auxilium transaction and are well positioned to capture synergies from the Par acquisition. In addition to our positive operating performance, we have an improving adjusted effective tax rate. We posted a third quarter 2015 adjusted effective tax rate of approximately 1%, and year-to-date, that rate is approximately 8.5%. As expected and guided on our recent earnings call, the quarterly tax progression will be lumpy due to technical accounting rules, the acquisition of Par and the continued implementation of actions to optimize our overall value chain.

The positive operating performance and adjusted tax rate led to third quarter adjusted income growth at a rate that was significantly faster than our revenue growth. Third quarter adjusted EPS from continuing operations of \$1.02 was lower than our revenue growth rates. Remember that this was impacted by our adjusted diluted earnings share count of \$211 million for the quarter, which reflect the additional shares issued as part of our Par financing and acquisition.

Moving to Slide 32. I will not review the year-to-date slides in depth. We believe that they are strong results that reflect the value created by our long-term strategy.

Before we talk about guidance for this year, full year 2016, I do want to take a moment to discuss the impairment charges we took in the quarter. As Rajiv mentioned earlier, we are accounting for pretax

noncash impairment charges of approximately \$240 million related to intangible assets and approximately \$680 million related to associated goodwill. These impairments represent 3% of Endo's total intangibles at the third quarter and approximately 9% of total goodwill prior to these respective charges. The intangible-related charges are primarily driven by the recent underperformance across STENDRA and certain TRT products in tandem with the expectation of lower future cash flows as we realign investment priorities towards higher-growth assets such as XIAFLEX and BELBUCA. In addition, our continued prioritization of higher-value products and development projects has led to the reduction in value primarily across our legacy Qualitest business.

The intangible asset charges related to branded products has triggered us to test goodwill across Urology, Endocrinology and Oncology reporting unit within the U.S. Branded segment, ultimately leading to a provisional impairment of associated goodwill in the quarter. I should note that our normal testing cycle for goodwill generally occurs in the fourth quarter. However, the charges related to STENDRA and TRT products compelled us to accelerate our evaluation of goodwill within certain parts of the U.S. Branded segment. So while we have taken a provisional charge in the third quarter, that charge may get adjusted up or down as we complete our enterprise goodwill testing in the fourth quarter of 2015.

The pretax noncash intangible asset and goodwill accounting charges in the third quarter are partially offset by a related \$80 million reduction in future contingent consideration. While we are disappointed with the performance of STENDRA and across certain parts of the TRT portfolio, we continue to be very excited about the long-term growth opportunities related to XIAFLEX and BELBUCA as well as our highly diversified and specialized generics portfolio and the International platforms. Most importantly, we continue to remain confident in our near-term guidance and our long-term aspirations.

So moving to Slide 34, we are reaffirming our full year 2015 financial guidance from continuing operations, which we updated around the close of the Par acquisition in September. We expect full year 2015 revenues between \$3.22 billion and \$3.27 billion and adjusted gross margin of approximately 64% and effective tax rate of 9% to 10%, adjusted diluted earnings per share from continuing operations to be in the range of \$4.50 to \$4.60 and reported or GAAP diluted earnings per share from continuing operations for the year to be within a range of minus \$3.70 to minus \$3.60. Remember, we have affirmed this guidance and maintained the upper end of our previous EPS range with 6 months of dilution from the Par pre-close financing activities and only 3 months of Par revenue for the full year 2015.

Overall, I am pleased with our year-to-date performance which continues to be characterized by solid underlying revenue growth, margin expansion and robust underlying cash flow generation, and I am excited about the opportunities that we have to continue with the transformation of Endo into a leading global specialty pharmaceutical company.

Now let me turn it back to Rajiv to close out. Rajiv?

Rajiv Kanishka Liyanaarchchie De Silva
Former Chief Executive Officer, President and Director

Thank you, Suky. Moving to Slide 35. As Suky said, we are strongly positioned for growth in 2016, and today, we reiterate our 2016 financial guidance of an estimated adjusted diluted earnings per share from continuing operations in the range of \$5.85 to \$6.15.

We remain confident in our ability to deliver double-digit revenue growth, strong and rapid synergy capture, continued progression and execution of our tax strategy and robust cash flows and rapid de-levering that enables continued execution of our M&A strategy.

To summarize. On Slide 36, I want to reiterate that we feel fundamentally that Endo is more diversified and stronger financially and strategically than ever before. We are positioned for growth. We have created a powerful platform for future M&A and we have built an expanded and diversified product portfolio and R&D pipeline. All of this against a very compelling backdrop of double-digit organic growth projected over our planning horizon.

That concludes our prepared remarks. Let me now turn the call back over to Keri to manage our question-and-answer period.

Keri P. Mattox

Former Senior Vice President of Investor Relations & Corporate Affairs

Thank you, Rajiv. We'd like now to open the line to your questions. [Operator Instructions] Operator, may we have the first question, please?

Question and Answer

Operator

[Operator Instructions] Our first question comes from the line of Louise Chen with Guggenheim.

Louise Alesandra Chen

Guggenheim Securities, LLC, Research Division

So first question I had here is what is driving your effective increase in '15 guidance post the close of the Par deal? And then second question here is, your double-digit growth of mid- to long-term aspiration, how much of that is driven by price versus volume? And then the last thing here is just how do you differentiate yourself from all this noise in the health care industry on pricing especially pharmacy? What's sort of the tagline here?

Rajiv Kanishka Liyanaarchchie De Silva

Former Chief Executive Officer, President and Director

Sure. Louise, let me answer your question on the contribution of price and volume to our double-digit growth and some comments about what's going on in the industry, and then I'll have Suky talk about our 2015 guidance that we reaffirmed today. So what's key about our business is that our business is not dependent on price as a driver of long-term growth. Now historically, if you look at our Branded business, that's primarily being driven by volume. And as we look forward into our Branded business, it is going to be driven predominantly by new product launches and growth of products like XIAFLEX, right? So it is fundamentally a volume growth story in our branded business. And then similarly, for our generics business, while historically, the Qualitest business did enjoy a certain amount of price since growth, now Qualitest itself has grown in the midteens organic in the last 5 years and 2/3 of that growth though came from volume and mix. Going forward, we expect the contribution of price to be much more muted because if you look at the Par acquisition and what Par brings to us, it's all about pipeline. And as we look into 2016 onwards for our generics business, our growth is predominantly going to be volume-based, and in our international markets price value is never a [ph] lever, so it's all volume. So if you step back from it, I think if you look at our double-digit growth trajectory over the next few years, it is going to be predominantly about volume. And in terms of your comments about what's going on in the industry around us, certainly, this has been a very choppy time for the specialty pharmaceuticals sector, but I would say in terms of the specific issues have been debated in the marketplace, for example, the issue of pricing and the relative roll price in place. I've already explained to you why we don't really feel too worried about that, because we are not really dependent on pricing going forward. We've commented previously and today about the role of intermediaries like specialty pharmacies and how we use them, where we believe we are very appropriate in our use of these intermediaries and they're really no different than other distributors that we use. So as we step back from this, certainly, our industry is going through a downturn. Now this is not the first time this has happened to our industry, but as an important thing for us is that we have all the tools that we need to write through this downturn, right? We've just completed transformational acquisition. We have a great pipeline of projects coming through on XIAFLEX. We just got BELBUCA approved. So for us, this is really about operating our business and executing, and we have very attractive business going into 2016 and beyond. And my belief is that the fundamentals of our industry continue to be extremely strong, and eventually, the market will come back and the companies that have underlying organic growth potential are the ones that are going to be successful and we count ourselves among those companies. So with that, Suky, you want to touch on '15 guidance?

Suket P. Upadhyay

Former Chief Financial Officer and Executive Vice President

Yes. So Louise, to your question on what are the drivers on the top end of our guidance post closing of Par, and I would say it's really coming across all elements of our P&L, which for me, represents a good quality approach to how we're achieving our guidance for this year. So first, from a revenue perspective, we've had some headwind on the legacy Endo business this year. If you think about foreign currency rates, with the introduction of an additional generic LIDODERM entrant with fairly steep price decreases, as

well as the underperformance of STENDRA, which we've been quite transparent about, the overall Endo legacy business continues to operate within the revenue range that we put out at the beginning of the year. And then if you think about Par, since we signed a deal to where we are today, that asset's actually performing on the top line a little bit better than what we originally expected. So overall, revenues are coming in right in line with how we thought about. Then from a P&L perspective, the reason why we're able to offset a half year of dilution from Par with only a quarter of the year of operating results from Par is really because our gross margin is performing better than we expected. That's primarily driven by the generics business. But if you actually look at Branded as well as the International segments, they're actually showing some modest improvement year-over-year as well on a year-to-date basis. Operating expenses are better than where we thought and that's primarily driven by a faster uptake of the Auxilium synergies, and that's also in the backdrop of stepped-up investment against STENDRA and now stepped-up investment against BELBUCA within 2015. And last, we are very pleased with our overall tax rate. There's a number of drivers against that. One is obviously the Auxilium as well as the Par transaction. But our underlying fundamental planning strategies around supply chain are also yielding some very nice and better-than-expected benefits. So really again, you're seeing that benefit across our entire P&L.

Operator

Our next question comes from the line of David Amsellem with Piper Jaffray.

David A. Amsellem

Piper Jaffray Companies, Research Division

Just a few questions. So I guess on the assets you wrote down, particularly the testosterone products, maybe give us your thinking on where you miscalculated when you did the Auxilium transaction. And I think where you went wrong or what you thought you got wrong about those assets. That's number one. And I guess the same question would be asked of STENDRA. And then secondly on BELBUCA, maybe this is early, but if you can talk about how we should think about price and what are the comparators that we should look at there, that would be helpful.

Rajiv Kanishka Liyanaarchchie De Silva

Former Chief Executive Officer, President and Director

Sure. David, let me touch on the testosterone market and STENDRA, then I'm going to have Brian talk about BELBUCA and our views on pricing there. So on the testosterone products, in the Auxilium transaction, there were 2 assets that came to us in testosterone space. One is TESTOPEL and the other is Testim. So most of this downdraft has been in Testim and I think there, really, the difference between where we will when we signed the Auxilium transaction and today is that there is much more significant generic competition for Testim and the market continues to decline at a double-digit growth rate, which has affected not only Testim but also FORTESTA as well as Natesto. So I think when we step back from this, one of the things that we take great pride in our business model is being rational actors, right? So we certainly believe in the transactions we do and the assets we support, but upon reflection, if there's anything that is not working as we think it will, we will divert resources to things that are more likely to create value, which is exactly what we're doing here. So the good news, though, about the testosterone market for us is that the 2 assets that we always thought were longer-term assets, which were AVEED and TESTOPEL, are collectively in a -- in the long-acting segment, which for us is growing. And we expect it to keep growing and that's where we expect to put our investment going forward. The STENDRA story is very simple, right? I think we are very clear that we expect -- we believe that based on what we found after we closed the transaction that this was a poorly launched product by Auxilium with a lot of miscalculation and missteps along the way. We put a lot of efforts against it to recover it including additional field efforts, some targeted BTC spend, et cetera. And while we are seeing some encouraging results from those investments, really, when you put that against the opportunity that we have with BELBUCA, it really pales in comparison, which is why we've taken the opportunity to reallocate resource. So just to finish off the discussion on Auxilium, I will remind you that for us, Auxilium really is about the XIAFLEX platform, and that continues to perform extremely well. In the end market indications, the pipeline is richer than we thought at the very beginning, so there's actually a lot of positives about Auxilium that we are very encouraged by. And as Suky said, we've overdelivered both in terms of size as well as timing on our

synergies, which has also been a big driver of success in 2015. So we are actually, overall, very pleased with the Auxilium transaction, and we believe that the ultimate view of its success or not should be taken with respect to the longer-term expectations for that business. So Brian, maybe you can comment on BELBUCA pricing and how we're thinking about it?

Brian Lortie

Former President of U.S. Branded Pharmaceuticals

Sure, happy to. Thanks, Rajiv, and thanks, David, for the question. We're obviously very excited about BELBUCA. We think we've got a very nice label and the first pass approval was a big success for our R&D team. We like the profile of this product. We think it's going to have a very important place in armamentarium of pain products on the market and being a product with a nice safety and efficacy profile accompanied by the Schedule III designation, we think that it's going to, as I say, fit in very, very well. I'm not going to guide too specifically on price. But I think if you look at the other long-acting opioids that are in the market treating chronic pain, you can get an idea of the range that we'll be playing in. Philosophically, our goal here is to provide access for as many patients as possible and also to provide access cleanly and smoothly on managed care formularies, and our conversations are underway behind that. But just -- as we've said, we had planned on stepping up in a major way to resourcing behind BELBUCA because we think it really provides us with a very compelling growth profile going forward. And frankly, we're excited to get it on the market as soon as we can in 2016.

Operator

Our next question comes from the line of Marc Goodman with UBS.

Marc Harold Goodman

UBS Investment Bank, Research Division

First, on XIAFLEX. I just want to make sure I understand. You said that for Frozen Shoulder and Cellulite, you have not met with the FDA yet, but you are planning to launch the studies literally in the next month. So I'm just curious, did I hear that right or you have met with them? Second, in the generics business, can you tell us how much the LIDODERM AG represented and what the gross margin was? And you started to talk about TESTOPEL a little bit, but is there any way you can give us just a sense of the revenues there and maybe what the revenues were when you bought it just to give us a sense of what's happened for that product.

Rajiv Kanishka Liyanaarchchie De Silva

Former Chief Executive Officer, President and Director

Sure. Let me answer the XIAFLEX question and TESTOPEL and then I'll hand it over to Suky for the LIDO AG. So on XIAFLEX, on both Frozen Shoulder and on Cellulite, there has been ongoing dialogue with FDA. However, prior to actually initiating the next Phase IIb study, our expectation is that we would want to have a confirmatory meeting with the FDA to ensure that we are fully aligned in terms of endpoints as well as patient population. So those meetings are being set up and for Cellulite has been set up. We're in the process of doing that for Adhesive Capsulitis/Frozen Shoulder as well, and we are hopeful that those will be bought by the end of this year, which will then allow us to immediately enter into the trial. So that's where we are in terms of time line. In terms of TESTOPEL, if you recall, there were some changes in TESTOPEL reimbursement that happened just in the backdrop of our acquisition, it actually happened before our acquisition of Auxilium. So there's been some rebasing of that product going into 2015, but we've seen a very nice stabilization of it and we expect it to -- along with AVEED contribute to growing long-acting franchise headed into 2016 onwards. Suky, why don't you just talk about the LIDO AG question briefly?

Suketu P. Upadhyay

Former Chief Financial Officer and Executive Vice President

Sure. So LIDO AG even in the backdrop of the most recent entrant on that product is still about 1/3 of the market. It's down about \$20 million to \$25 million within the quarter and gross margin of the profile of

that product subsequent to the new entrant is somewhere around or maybe slightly below the division or segment gross margin average in the mid-50s.

Marc Harold Goodman

UBS Investment Bank, Research Division

So gross margin for the whole generic business is mid-50s this quarter?

Suketu P. Upadhyay

Former Chief Financial Officer and Executive Vice President

That's right.

Operator

The next question comes from the line of Chris Schott with JPMorgan.

Christopher Thomas Schott

JP Morgan Chase & Co, Research Division

Just with some of the recent stock market and fixed-income moves, any changes in priorities for capital deployment? I guess, where does share repo fit versus debt paydown? Are you seeing any signs of -- from sellers that price might be resetting given market dynamics? And then my second question was just building on some of the earlier comments here. Are there any learnings from the Auxilium transaction that we should think about as you look at future deals in terms of either things you would or wouldn't do, or the way you'd manage acquired products? I'm trying to understand that a little bit better.

Rajiv Kanishka Liyanaarchchie De Silva

Former Chief Executive Officer, President and Director

Thanks, Chris. In terms of capital allocation, and I think we've always been very clear in terms of where we are in our corporate cycle of rebuilding the company and repositioning it, that for us really capital allocation was in the following order, which is towards new acquisitions and also, obviously, funding organic growth; debt paydown next because we do believe in maintaining an attractive balance sheet; and then share repurchase, which came at the end of those priorities. I think as we sit here now, clearly, from the standpoint of where we see our own shares trading, we believe we are substantially undervalued. That being said, we don't want to lose sight of the fact that our fundamental mission here is about growing the company and creating long-term value, and we do continue to see some very attractive assets out there. And as you pointed out, prices have come down substantially. And with the Par transaction just closed, we will be rapidly de-levering going to 2016 and with an EBITDA base in excess of \$2 billion. So we will very soon be in a position with substantial resources to pursue acquisition, so that will be our priority. We certainly take the obligation that we have to pay down debt very seriously, that's a commitment that we made to rating agencies as well as the shareholders. So we intend to do that going into 2016 as well. And of course, from time to time, our board will take a look at share repurchases as a strategic alternative to capital allocation, but I would say we do continue to see some very attractive opportunities to continue to build the company, which is quite encouraging. In terms of your question on Auxilium, as I explained in my previous answer, the core expectation that we had in the Auxilium transaction, which was acquiring a very long-term platform, has proven to be exactly the case, right? And then certainly, in terms of what we found with this XIAFLEX platform both in terms of on-market indications and the pipeline continued to be at or above our expectations. Certainly, the pipeline is well above. And however, I think there's always learning -- there are always learning opportunities every time we do a transaction. So when I step back from Auxilium, I would say there were 2 learnings that we had. One is I think we've always said that for us to play in predominantly primary care type products, it's going to be difficult, and we prove that ourselves again with STENDRA. And in particular, relaunching a primary care product in a very crowded competitive market where there's a lot of money being spent, it's not something our business model is intended for. And I think so that certainly informs how we might think about the opportunities like STENDRA in the future. And the other thing that I think we've also been very clear in terms of some of the commentary that we made in the last couple of quarters is that we did not -- we had to move to make some corrections, particularly around the reimbursement support that we had for XIAFLEX in terms

of continuing the products' growth, which we probably were not fast enough, right. So those are the 2 learnings that we have. But overall, I would say that the other types of things that you worry about in integration, which is synergy capture, keeping a compliance mindset in a transition, all of those things have gone extremely well. So net-net, if I step back from the Auxilium integration, I'm actually quite pleased with it.

Operator

Our next question comes from the line of Annabel Samimy with Stifel.

Annabel Eva Samimy

Stifel, Nicolaus & Company, Incorporated, Research Division

I guess it's similar along the lines of the prior question, but right now, you've got some of the best-performing assets and brands that are some of the oldest ones or potentially going away. And we're excited about BELBUCA and continued opportunity for XIAFLEX. But with these assets, do you feel that you're in the right areas of growth right now? And can you get to the double-digit growth with these assets and what can we expect with regard to M&A in this, I guess, revalued marketplace? I know that you're interested in that, but are you refocusing some of the areas that you're moving into? And on the generics side, what has allowed you to take some -- take advantage of certain pricing opportunities where other competitors in the same areas have not been able to?

Rajiv Kanishka Liyanaarchchie De Silva

Former Chief Executive Officer, President and Director

Thanks, Annabel. So in terms of your question on the Branded business and double-digit organic growth, I think what we've been clear about is that for the company as a whole, we expect to be in double digits in our planning horizon. Our Branded business is likely to be in the high single digits, where we stand now, and that's obviously before the impact of the XIAFLEX pipeline, which happens in the very end of our planning horizon. So if you look at our Branded business and think about XIAFLEX, think about BELBUCA, that is a big component of how we expect growth to be supported in the next little while, but let's not forget, I mean, we have products like SUPPRELIN LA, AVEED, which are doing quite well. TESTOPEL, we are confident will swing back into growth. So we actually have a nice table of products that we expect to contribute to growth. And Voltaren Gel is a bit of a wildcard. It's a product that has grown very nicely under our watch. Our promotional agreement comes to an end in mid-2016, but we continue to have a dialogue with GSK and Novartis joint venture around potentially extending that, and that we will be -- we've been clear that, that would be something that we'll be very interested in doing and we've disclosed that in prior earnings calls. And we continue to have those dialogue and we are hopeful that they will be resolved in the near term. In terms of your question on M&A, and I suspect your question was mostly focused on the Branded arena, one of the things that we've said consistently is that, we need to build further critical mass in our Branded business. So right now what we have are essentially 2 legs, which is the pain business, which now has a good flagship product, BELBUCA, right in the front end; OPANA ER behind and, hopefully, Voltaren Gel on an ongoing basis; and then we have a specialty products business, which is led by XIAFLEX with TESTOPEL and AVEED in the portfolio as well. But for us to really aspire to leadership in Branded, I think we do need another platform. Our views on what those platforms are, frankly, have not changed very much. I think for us, it's all about the right opportunistic entry where we think we can create value and that's certainly what we're going to be looking for as we head into 2016 and 2017. And finally, on your question on generics, [indiscernible] this is mostly a Qualitest question, so I'll take it and maybe I'll ask Paul to comment on his view of generics going forward. For us, the Qualitest portfolio had 3 legs, right? There's pain -- sorry, there's controlled substances, there is liquids, and then our portfolio of very small products of which we have up to 800 products, right. And smaller products that a lot of the big competitors don't make anymore, we're often competing with small players. The controlled substance space has been one where there's been events that allow for price increases like the off scheduling of the hydrocodones. And the small products, an area where oftentimes, the supply/demand dynamics are such that there are opportunities for pricing. Because many of these don't last very long, they're temporary, but net-net they have contributed to Qualitest growth. However, we've always been -- also been clear that it was not our expectation that opportunity will continue forever, right? I think this will

be a diminishing opportunity, which is why prior to the acquisition of Par, we signaled Qualitest to be high single-digit growth versus a double-digit growth. So hopefully, it answered your question, but maybe Paul, you can comment a bit on your views on pricing and generics going forward.

Paul V. Campanelli

President

Yes, sure. Thanks, Rajiv. I mean, again, I think clearly, when we look at -- on a go-forward basis, Rajiv talked a little bit about the narcotics, and maybe, I kind of view that as technically challenging our products. I would look at it the same way on a go-forward basis, to be very select, right? So from that standpoint, you're not going to see me-too products seeing price increases. I think where we see going is going to be driven on volume and that's really where the Par portfolio comes in, in terms of new R&D products that we're looking to launch, and it's really about operational execution and getting the pipeline approved as quickly as possible. But I think it's going to be a little bit more challenging across the board on price increases. As you see, the consortium is getting a little bit bigger, but we have to execute on the pipeline and I think that's really the story here.

Operator

Our next question comes from the line of Liav Abraham with Citi.

Liav Abraham

Citigroup Inc, Research Division

A couple of questions. Firstly, Paul, can you comment on how Par performed in the quarter and why that it wasn't consolidated -- the results weren't consolidated but it would be helpful to get a sense of the performance of the business and also any meaningful catalyst on the Par side that we should look out for over the next 6 to 12 months? And then secondly on pricing, Rajiv, in the unlikely event that politicians are able to collapse Medicare rebates to Medicaid rebates, can you frame the potential top line impact to your Branded business?

Rajiv Kanishka Liyanaarchchie De Silva

Former Chief Executive Officer, President and Director

Sure. So just, I will -- before I hand it to Paul, I just want to remind you that we only consolidated 4 days of results so far, so we're not going to comment on the financials of Par in the third quarter. However, Paul can certainly comment on the qualitative aspects of how the business did in the third quarter and the highlights as well as his views going forward. But again, we're not going to provide any specific revenue or profit numbers specifically for Par for the remainder of 2015 either. Paul?

Paul V. Campanelli

President

Well, I'll just be real general and leave. I think to Rajiv's point, I mean I'm real proud of where Par has landed over the last several quarters and really in the way we kind of look on a go-forward basis to really, at the end of the day, we performed as we predicted, right. So I think that's probably the best way of putting it at this time. Without giving any specific numbers, the team continues to execute and we delivered on what we had promised to the Endo team.

Rajiv Kanishka Liyanaarchchie De Silva

Former Chief Executive Officer, President and Director

Maybe Paul wants to comment what he thinks drivers are going to be in the next 6 to 12 months.

Paul V. Campanelli

President

Yes, so at the end of the day, we keep on talking about this operational execution and we still have a portfolio of products that we have to work with the FDA and we're excited about the portfolio. We certainly -- in the slides that we've shown, we have a series of products that we're excited about, notably the

[indiscernible] and ezetimibe products that we are planning on executing and deliver as we get into 2016. And overall, we have our goals and objectives on the number of applications that we need to file and we have a very strong focus on filing products, launching products. Again as we file, we need to get them out of the FDA and we have to drive our sales. So ultimately, we have our plan to continue to file in the area of 20 to 30 applications on an annualized basis, and our goal is to launch as we forecasted. So, so far, very excited about the prospect of execution.

Rajiv Kanishka Liyanaarchchie De Silva

Former Chief Executive Officer, President and Director

Perfect. Suky, do you want to cover the Medicare-Medicaid rebate question?

Suketu P. Upadhyay

Former Chief Financial Officer and Executive Vice President

Sure. So I think the first thing to understand is it's important [ph] it's a very diversified portfolio even within our Branded business where no one product accounts for more than 6% of revenues. If you have to think about Medicare moving to Medicaid-like rebates or discounts, the way we've framed that in is that at a company level, the impact would be in the low single digits.

Rajiv Kanishka Liyanaarchchie De Silva

Former Chief Executive Officer, President and Director

As a percent of revenue.

Suketu P. Upadhyay

Former Chief Financial Officer and Executive Vice President

As a percent of revenue, yes.

Operator

Our next question comes from the line of Andrew Finkelstein with Susquehanna Financial.

Andrew Jay Finkelstein

Susquehanna Financial Group, LLLP, Research Division

I was hoping you could help us, I know you don't want to give the Par figure specifically for the quarter, but within generics, we had talked earlier in the year about some of the quarter-to-quarter dynamics within the Qualitest business, if you could give an idea of some of the moving pieces there. I think in the second quarter, you had talked about a \$16 million stocking benefit but also the impact of the price increase penalties. And then moving into third quarter, I think the expectation was you'd get the benefit of the increases that we're taking in the second quarter. So you could talk it all about how much the net realized price was relative to your expectations and what the benefit is going forward and in any of the key products from the Qualitest business, whether that's Valcyte or the potassium product in the controlled substances portfolio, just any idea of what's -- any big changes on particular products? And then finally, on the Par business, I think the working capital profile looked, at least as of the last quarter, a lot different for Par versus your business. So just any comments there about how those -- how that changes as their customer terms are folded into your contracts.

Rajiv Kanishka Liyanaarchchie De Silva

Former Chief Executive Officer, President and Director

Sure. Let me start on this, and I'll have Suky answer. So we're not, for example, on things like customer contracts, we're not going to comment on it. That's something that Paul is right in the midst of. He's handling that himself personally because it's such an important topic, and we will see the outcome of that going into next year. But on your questions on Q3, the impact of price, et cetera, just to make sure that we set the fact straight, when we took our price increases in the back end of Q2, we were clear that the level of the pipeline accruals and price penalties that we're paying would mean that the real net benefit of those price increases would likely happen in the very back end of the year and more importantly for

2016, right? So in Q3, there is no benefit from this price increase. In fact, the price penalties actually continued to drag down Q3 results, and the result of our Q3 growth in Qualitest is all volume, and really, there is no price in it. And we continue to be very pleased with the performance of Valganciclovir, the potassium chloride product and the Hydro-APAP. And we've signaled that we expect some competition for the low-dose Hydro-APAP and Valgan sometime in the fourth quarter maybe continuing to expect that, but certainly, in terms of how they perform in Q3, we're very pleased, and we are also, from what we can tell, off to a reasonable start to the cough/cold season. The outcome of the cough/cold season will only be known in Q1. The shipping for the cough/cold season began in Q3, and it was a reasonable outcome for that business as well. So do you want to comment on the Par working capital?

Suketu P. Upadhyay

Former Chief Financial Officer and Executive Vice President

Sure. Just to reiterate on the generics piece, sequentially, even excluding Par, the Qualitest business did grow from Q2 into Q3, and that's even in the backdrop of a steeper price decline in LIDO AG than we originally anticipated. So the business fundamentally is still performing quite well. Regarding working capital, I think the first thing to understand is there's a little bit of noise whenever you acquire a business like this so late in the quarter and how that impacts working capital. So first, as a part of opening balance sheet at the acquisition of Par, you're going to put the full inventory balance in the full AR and AP balances, but you've only got essentially 4 days of operating results as part of your denominator. So that's going to skew your working capital pretty significantly. But the way I would think about Par is that on a DSO basis, they're probably slightly better than the overall company average for Endo, which we currently see as somewhere around in the low 50s. From a DPO standpoint, Endo's probably a little bit better, and where I'd see that is the average of somewhere in the mid-30s. And then on an inventory basis, both companies are relatively at the same level, which is at about 60 days.

Operator

Our next question comes from the line of Gary Nachman with Goldman Sachs.

Gary Jay Nachman

Goldman Sachs Group Inc., Research Division

Rajiv, when do you think we'll start to see even more of an inflection with XIAFLEX? How exactly have you adjusted formulary support for it? And if you're removing some of your focus from urology, could that potentially hurt uptake with Peyronie's? And then on BELBUCA, how much of that uptake will be driven by primary care since you said that's not a great place for you to compete? And did you actually get confirmation at schedule 3?

Rajiv Kanishka Liyanaarchchie De Silva

Former Chief Executive Officer, President and Director

Sure. On XIAFLEX, let me -- I want to actually hand it over to Brian to talk about some of the things that we're doing vis-à-vis Peyronie's and DC for the next year. But what I would say is that in terms of a inflection point, DC is expected -- I would continue to think about DC as a steady grower. Certainly, at some point, the MULTICORD indication will begin to kick in, we hope, in a more substantial fashion, but I'm not sure that's going to create inflection other than to continue to sustain the growth trajectory. Peyronie's also, I believe, is going to continue to grow and it's certainly at a higher growth rate than DC. And actually, whether there is a single inflection point or a sustained inflection over time is yet to be seen because I think our biggest area that we need to create further momentum before that is patient education and getting more patients into the funnel. We already have a pretty nice set of injector base and the additional dynamic there we need to see is to really increase the number of truly active injector. So maybe, Brian, you can talk a bit about exactly what we're planning on doing.

Brian Lortie

Former President of U.S. Branded Pharmaceuticals

Sure, happy to do that, and thanks for the question, Gary. Before I do, though, let me just reinforce the difference between our specialty urology capabilities and our retail urology capabilities. So our specialty

team, which is really anchored, as you know, by XIAFLEX, has a dedicated team in specialty urology, XIAFLEX, AVEED, TESTOPEL, and there will be absolutely no change to that business. We think we've got that business on the right foot now. With everything from demand creation to reimbursement support, we're very excited about what they can deliver going into 2016. So I just wanted to underscore that. And in fact, as we do reprioritize away from STENDRA, we have a customer continuity plan in place that we will execute very carefully to make sure that there is no disruption there. So just wanted to make sure we were clear on that. As Rajiv said, on XIAFLEX, we're actually very, very happy. We've got year-on-year growth of about 20% plus and underpinning that, even after 5 years of launch, is about 14% on Dupuytren's. And we think as we've learned more about XIAFLEX going into 2016, there's some untapped opportunities for growth and how we think about the channels and creating and supporting demand beyond, let's say, the core launch group of injectors, and we will step into that in a big way. One of those ways is with patient engagement. And as we spoke to, we already have started the early stages of patient engagement direct-to-patient campaign intended to make sure we're flowing patients into our prescribers, while at the same time, we're working to grow the prescriber base. So we like the prospects very, very much. We like what we see in terms of vials per patient in both Dupuytren's as well as Peyronie's. And frankly, we're just excited by and will continue to step into XIAFLEX going forward. You also asked about BELBUCA relative to targets. So let's be clear there. Any primary care docs that we -- and frankly, this is consistent, I think, with most players in the market, any primary care docs that we target really are acting more like pain specialists than typical broad primary care specialists. So we'll allocate our selling against that. So we don't think of this as a big primary care play necessarily. And in doing so, we'll target. We think the profile of the product will lead to some great uptake. And then your C3 question, we see this as a C3 product. That's based on the fact it's buprenorphine, which has been well established and already scheduled, so kind of uniquely, we get to take advantage of that, and we'll bring the product to market accordingly.

Gary Jay Nachman

Goldman Sachs Group Inc., Research Division

Okay. But did you get confirmation at C3 yet or you're waiting to hear from the DA on that?

Rajiv Kanishka Liyanaarchchie De Silva

Former Chief Executive Officer, President and Director

So Gary, the way this works is that the scheduling is for the class because this is a well-established molecule that's been around. And unless the DA takes specific action against the entire class, we don't expect action specifically on BELBUCA at this point.

Operator

Our next question comes from the line of Gregg Gilbert with Deutsche Bank.

Gregory B. Gilbert

Deutsche Bank AG, Research Division

Just a couple of quick follow-ups on XIAFLEX. I don't think this came up yet, but can you talk about the net price? It looks like the implied net price was down in the third quarter from the second quarter. So can you confirm that and talk about what's going on with that? And can you also talk about how you expect the average file utilization to grow from current level, whatever the current level is, as the mix of the business continues to shift by indication?

Rajiv Kanishka Liyanaarchchie De Silva

Former Chief Executive Officer, President and Director

Again, let me have Brian talk about the vial issues, but XIAFLEX is not a product in which there's any substantial price movement. There's a big component of just buy and build, so that really restricts us, in any case, in terms of the types of price increases that we take, and also it's not a product that is broadly discounted or rebated either. I mean, there are some very, very controlled areas in which there are some volume discounts that are given, but they're not substantial. So there really is no movement on XIAFLEX on pricing very much. Maybe Brian, you want to talk about the vials?

Brian Lortie

Former President of U.S. Branded Pharmaceuticals

Sure, happy to do it, Gregg. So in Peyronie's, we're sitting at about 4.5 vials per patient. There's the chance for that to migrate upward a little bit, but we don't build that necessarily into our expectations. It's a different story, however, for Dupuytren's because, as you know, we're still early in the MULTICORD rollout, and we're actually, frankly, pleased with the fact that it's migrated up a bit from 1 to 1.2, and we do see some potential for that to grow, obviously, to 2 vials over the next coming months or so.

Gregory B. Gilbert

Deutsche Bank AG, Research Division

And then maybe for both of you, a bigger picture question on XIAFLEX. Not to look backwards too much, but can you talk about changes made in people and programs and post acquisition? And are you confident that you have the right sort of resourcing behind you? I ask because investors are very concerned these days about acquisitive companies that sometimes have to reset the bar on products they've acquired or lower expectations after ownership. So just maybe a bigger picture question that you could address on XIAFLEX and how you're resourcing it? I know it's an important long-term driver, but can you talk about some of the specifics?

Rajiv Kanishka Liyanaarchchie De Silva

Former Chief Executive Officer, President and Director

Certainly, let me start, and then Brian, you can add to it. We've made some changes on the XIAFLEX team after we bought the brand. We have Blaine Davis, who runs the franchise for us, we have a new individual who runs the sales efforts on the urology side and a very strong individual who runs the sales efforts on Dupuytren's. We've also changed over our managed care efforts and reimbursement efforts. So I would say at a senior level, I'm confident in the team that we have. And then maybe Brian, you can talk about at a more specific level, any observations you have.

Brian Lortie

Former President of U.S. Branded Pharmaceuticals

Yes. I think I would just say exactly the same thing. Like any integration, you're going to have some turnover. What's important to recognize is that we were successful in bringing over and retaining, especially in the sales and reimbursement arena, some very experienced and talented people, who knew the product very, very well, and they've continued to stay with us. And again, I'll reinforce that, especially in reimbursement where, knowing the product, knowing the customers and understanding the intricacies of access for our patients were so critical, and the vast majority of those people remain and are engaged and producing very, very well. And as Rajiv said, we made some changes at various levels, but we're very, very happy with the people that we're able to bring on. And frankly, coming out of the disruption, we've talked about already earlier in the year, we think we're on a very solid footing, and we're very happy with the growth trajectory going forward.

Rajiv Kanishka Liyanaarchchie De Silva

Former Chief Executive Officer, President and Director

And the other thing that I would say, Gregg, is that if you look into 2016 actually, our resourcing behind this brand will be higher than it would ever have been under Auxilium, both in terms of sales, in terms of other support we're going to put around patient engagement, patient awareness, and more important, the R&D spend on this product, which is -- it's going to become much more robust headed into '16, '17 and beyond in a way that Auxilium could not have the resource before. So I would argue that for the co-franchise that we acquired in Auxilium transaction, the resourcing is actually going up.

Operator

Our next question comes from the line of David Risinger with Morgan Stanley.

David Reed Risinger

Morgan Stanley, Research Division

I have a couple of questions. First of all, with respect to XIAFLEX, it seemed like the year-over-year growth versus what was reported in the September quarter last year was 3%. Could you just walk us through how we should think about volume growth versus, I don't know, inventory changes or other swings to connect the dots between some of the growth figures that you've provided in volume and the year-over-year sales growth? And then second, with respect to BELBUCA, could you just sort of paint a picture for formulary access, specifically, how long it will take and what your targets are for formulary access for that launch?

Rajiv Kanishka Liyanaarchchie De Silva

Former Chief Executive Officer, President and Director

Sure. Let me see if -- Suky, do you want to take the XIAFLEX question?

Suketu P. Upadhyay

Former Chief Financial Officer and Executive Vice President

Sure. So in the third quarter this year -- I'm not sure what you were referring to sort of low single digits, David, but in the third quarter this year, XIAFLEX grew in the mid-teens. As we -- Rajiv talked about, price is not a major driver either up or down for that product, especially given its buy and build profile. Relative to your questions on inventory, this -- because a large component of both these indications is, in fact, buy and build, you do not have large inventory positions out in the channel or do you see large inventory swings. So inventory was not a major driver of growth in the quarter.

Rajiv Kanishka Liyanaarchchie De Silva

Former Chief Executive Officer, President and Director

Yes. If anything, inventory in XIAFLEX is a little bit lower. It's typically somewhere between a week and 2 weeks, and we're probably in the lower end of that spectrum. So inventory was not a driver of it either.

David Reed Risinger

Morgan Stanley, Research Division

And I'm sorry, what was the revenue booked last year for XIAFLEX in the third quarter? Maybe I had it wrong, but I was trying to calculate off of what was booked last year in the third quarter by Auxilium?

Rajiv Kanishka Liyanaarchchie De Silva

Former Chief Executive Officer, President and Director

Suky, do you...

Suketu P. Upadhyay

Former Chief Financial Officer and Executive Vice President

I think it was -- as I said, everything I'm talking about is sort of pro forma for Q3 versus last year.

Rajiv Kanishka Liyanaarchchie De Silva

Former Chief Executive Officer, President and Director

I'm sorry to interrupt. So one thing to keep in mind is Auxilium used to report x U.S. revenue of XIAFLEX together with the U.S. revenue, so just to be clear what we're talking about here are U.S. revenues.

David Reed Risinger

Morgan Stanley, Research Division

And do you know what the U.S. revenues for XIAFLEX were in the third quarter of last year?

Rajiv Kanishka Liyanaarchchie De Silva

Former Chief Executive Officer, President and Director

So that's what we're getting to '15. '15 is the growth calculation from. Brian, do you want to cover the BELBUCA?

Brian Lortie

Former President of U.S. Branded Pharmaceuticals

Sure, yes. David, you also had a question, so let me hit that quickly on formulary access. As we commented before finalizing our pricing, and as I said, our goal is to make sure we have access for the majority of patients, we're beginning our engagement with payers right now. I'm not going to guide specifically to how we think that will shake out, but again, I'll point back to the profile of the product, and we think it is differentiated within the space, and therefore, we are optimistic that we'll be able to get solid formulary access going into 2016 that will enable a sharp uptake once we launch.

Operator

Our next question comes from the line of Jason Gerberry with Leerink Partners.

Jason M. Gerberry

Leerink Partners LLC, Research Division

Just 2 from me. First on XIAFLEX for cellulite, just curious, the product that's priced right now based on what we saw in Phase II isn't priced for the cash-pay cosmetic market. So just kind of curious, as you think about the Phase IIb, having a commercially viable formulation or dosing format, whether or not you expect to have that in place for the Phase IIb or if that's something that you have to work on subsequent to the Phase IIb? Any thoughts you can provide just in terms of what that dosing format might look like, be it prefilled syringe or something else? And then my second question, just on international pharma, can you let us know what was the year-over-year growth of that business on a constant currency basis and how do we think about the impact of these divestitures in 2016? Just kind of wondering if we have more rebasing in '16 before we get to your growth outlook for that segment?

Rajiv Kanishka Liyanaarchchie De Silva

Former Chief Executive Officer, President and Director

Sure. Just let me quickly cover the cellulite question. I think the short answer is this is still something that is in discussion with the FDA. I think the most important thing for us is to -- with the FDA to come to agreement on the clinical endpoint. The commercial format of the product, the formulation, the -- whether it's prefilled syringe, the actual volume of it and therefore the pricing of it is a topic that we will continue to evolve. But I think the priority now is to find a clinical endpoint that is acceptable to the FDA. And then Suky, can you just cover the international business briefly?

Suketu P. Upadhyay

Former Chief Financial Officer and Executive Vice President

Sure. So international year-to-date has grown 19%, but again, that's partly due to the midyear acquisition. Foreign currency has had a headwind on the business through the 9 months of about \$20 million in top line. And the way we would see underlying growth is somewhere around negative 10%, and that's, again, primarily driven by the transition we're taking in a number of our businesses, specifically with Litha, as we talked about a divestiture, which has impacted sales in that business unit between now and when we actually closed it across vaccines as well as our medical device distribution business. Within Somar, we've seen that the change of control of a couple of products also impact that growth rate, and the same is true within Paladin. Going into 2016, those impacts are largely behind us, but we will continue to see a slight or modest step-down in 2016, primarily due to the loss of the revenues from the divestiture in Litha. But I will say that while we should see a modest step-down in overall revenues, those revenues were of very low margin, specifically because they were in vaccines as well as device distribution. So our overall EBITDA contribution for the business will actually increase into 2016.

Operator

Our next question comes from the line of Irina Koffler with Mizuho.

Irina Rivkind Koffler

Mizuho Securities USA LLC, Research Division

I just wanted to revisit the reorganization for next year with the sales forces. Is there an opportunity there to gain additional cost efficiencies? That's the first question. And then the second question is, going forward, do you see the company doing these smaller deal transactions, like NATESTO or Sumavel, or are you going to be focused on larger opportunities? Because it seems like those little things are the ones that haven't been working as well.

Rajiv Kanishka Liyanaarchchie De Silva

Former Chief Executive Officer, President and Director

Thanks, Irina. So in terms of the changes in the business going into 2016, this is really not about cost reduction, it's really about optimizing and expanding to support the launch of BELBUCA. So we really are in growth mode in our branded business from that standpoint. With respect to the smaller transactions, what I would say is that each of these transactions need to be viewed in the context of the circumstances under which they were done and what the facts are today, right? So similar for example, we did have a time where we had another excess capacities on pain field force, it was a nice tuck-in. And I would say in terms of the contributions made, it is in line with what we would expect. Are we thrilled about this performance, and is it going to be a huge growth driver going forward? Absolutely not. But at the time we did it, it filled a very important need for us. NATESTO is a novel delivery system. And at a point in time when we thought that the gel market would recover quickly, it seemed to be a good opportunity, and it might still be a great product. However, what I would say is that for us to maintain a retail urology field force just to support NATESTO is not viable, and it would have been viable only if STENDRA also was performing well, which is why we're taking the action via on NATESTO. So really it's not a reflection on our view on that product itself, it's really more about the viability of maintaining the field force just for that product.

Operator

Our next question comes from the line of Randall Stanicky with RBC Capital Markets.

Randall S. Stanicky

RBC Capital Markets, LLC, Research Division

Rajiv, I just want to go back to the share repurchase question. I mean I'm looking at the stock now, it's down 7%. You've got \$836 million in unrestricted cash in the balance sheet. You've not been shy about issuing equity to do deals in the past. So why not go back, buy back stock, send the message to the market right now and then use equity to finance deals at higher prices should the stock recover? And a related question to that is given the pullback in the stock and the leverage, you're roughly 4x on a trailing basis, what is your ability to finance some larger acquisitions? And maybe specifically, what type of deals should we be thinking about you guys looking at?

Rajiv Kanishka Liyanaarchchie De Silva

Former Chief Executive Officer, President and Director

Thanks, Randall. So look, and I'll repeat the answer I gave on the share repurchase, which is that it is within the various levels that we have. We have a active and ongoing discussion with our board in terms of how we allocate capital. So I'm not necessarily ruling out share repurchase. All I'm stating is that in a market like this, we need to keep our head on straight, and we have a lot of resources at hand and assets that are growing. And we also need to be mindful that we want to keep paying down our debt, right, and that there are many targets around us, but it's the smaller ones that are becoming much more within range. And I think that leads to my answer to your question, which is that in the very near-term, we're going to continue to be focused on smaller transactions that we can do on a all-cash basis. Obviously, at this level, we'll be very, very prudent about how we think about using our equity. At the same time, we're also open to the concept of doing large and more transformative transactions where it's not so much a value of equity but rather the relative valuation that might actually come into play, right? So in that sense, we continue to see opportunities. We're also going to be patient in terms of how we evaluate opportunities, but you can be certain that we have a very active ongoing dialogue with our board about how we allocate capital.

Operator

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The next question comes from the line of Corey Davis with Canaccord.

Corey George Davis

Canaccord Genuity Limited, Research Division

I just have 32 questions, so it shouldn't take that long. The first one is on your ANDA pipeline. What is the average time for ANDA approvals? And are you expecting or experiencing the same degree of frustration that other generic companies are? And then I have one more quick question.

Rajiv Kanishka Liyanaarchchie De Silva

Former Chief Executive Officer, President and Director

Paul?

Paul V. Campanelli

President

Sure. So it's a hard question to answer because the majority of our portfolio or Paragraph IV, so we're tied into the 30-month stay. And if you go through an appeal process, you're out 4 to 5 years. I would say, when I look at the real answer to the question, are we hitting our time lines when we have our earliest entry, I would say yes. So I'm not saying a -- generally speaking, a backlog on the Par portfolio. So with that, the Paragraph IV timelines allow us to catch up when we're in a situation. I've got -- I'm not going to say that's across the board on every product, but we have a small percentage of products that get backlogged, but the vast majority we hit are timeline spaced upon the 30-month stay.

Corey George Davis

Canaccord Genuity Limited, Research Division

And second question, it still wasn't clear to me, are you guys still investing in the testosterone market? And would you find that an oral testosterone would be effective? Or is this market just going to keep declining forever, and regardless of whether or not you have an oral or the best testosterone ever, it's just not a market where you want to be?

Rajiv Kanishka Liyanaarchchie De Silva

Former Chief Executive Officer, President and Director

So just to be clear, Corey, so we will continue to invest in the long-acting testosterone space with respect to AVEED, and AVEED is finally kicking in, in terms of its launch trajectory. And TESTOPEL, we believe, is going to recover. So I think we do think that there's a nice runway for the long-acting testosterone. In terms of oral therapies, and it is entirely possible that there will be a change in this marketplace one day when there is a viable oral therapy. The question is will there be one and when? Maybe, Brian, you can comment on that.

Brian Lortie

Former President of U.S. Branded Pharmaceuticals

I mean, I really don't have anything to add. I think it comes down to product differentiation. And as Rajiv says, if there's a truly differentiated product that has an acceptable safety and efficacy profile, it has the potential to perform well. But again, you have to look at the gel market, which has declined significantly over the last couple of years and that's led us to refocus into the area that we think gives the most compelling opportunity for growth, and we'll continue to support those products very, very strongly, both of which are in our specialty business, that, as we've said, we'll be stepping up our investment overall in that business.

Operator

Our next question comes from the line of Austin Nelson with Nomura Securities.

Austin Nelson

This is Austin on for Shibani. Just bigger picture, the comments that you made differentiating your use of specialty pharmacies from -- some use of some of your peers, we're really just wondering -- we understand that your products are kind of traditional specialty pharmacy products, but we're wondering if, in your view, you see anything wrong using them for more primary care or even specialty-type products that aren't necessarily physician-administered and also if you think that the use of distributors really makes sense long term, too. And then we had just one other one. On the reprioritization, is there potential to divest some of the assets that you're deprioritizing? I mean, as you pointed out, STENDRA, it's not so -- part of the issue is that primary care doesn't make sense for Endo, but could it make sense for someone who is in primary care and at least extract some value for Endo shareholders?

Rajiv Kanishka Liyanaarchchie De Silva

Former Chief Executive Officer, President and Director

Yes, so on the question on specialty pharmacy, I really can't comment on other companies' use of specialty pharmacy. All I can say is that they're a very valuable channel for us in terms of reaching the physicians that we need to with some physician-administered products, in particular, and it's still a very important role for patients who rely on those physicians. I would also say there's a big and growing portion of our vision that is buy and build, which is largely speaking, a service by specialty distributors who are, of course, different than specialty pharmacies. And again, we think it's a very important channel for us to be able to serve the needs of the physicians who rely on the buy and build channel, right? So from that standpoint, we continue to think that they're an appropriate vehicle and channel to use for our products that are more complex, have a more complicated supply chain, a pull [ph] chain, for example, and are physician-administered. In terms of your question on the reprioritization and how we think about those assets, it's important to note that on both STENDRA as well as NATESTO, we have partners. So you can imagine that we are in active discussions, and we'll be in active discussion with these partners in terms of finding the appropriate promotional setting for the products. And if that means the product needs to be in someone else's hands, we are very open to that as well.

Operator

Our last question comes from the line of Tim Lugo with William Blair.

Raju Prasad

This is Raju on for Tim. Just a quick one on BELBUCA. Is there a plan to apply for ADF formulation language on the label, and given OPANA ER, I assume those were in vitro studies that were done to support the SNDA?

Rajiv Kanishka Liyanaarchchie De Silva

Former Chief Executive Officer, President and Director

Brian, I don't know if you have a perspective on that?

Brian Lortie

Former President of U.S. Branded Pharmaceuticals

Sure, so yes. I mean, with OPANA ER, the agency, as I think we've spoken about before, did ask us to do some abuse liability trials, which were in vivo and inpatients. On BELBUCA, in terms of ADF, we currently are not contemplating that, although we'll watch. Remember, buprenorphine, in its own way as a molecule, is inherently less prone to abuse because of the lack of euphoria, and we see this across the existing products. And that, coupled with the dosage formulation, we think kind of gives it a differentiation based on that, but we don't plan to actively promote on that. We think that the efficacy and safety profile differentiates the product very well.

Operator

At this time, there are no further questions. I would like to turn the call back over to Keri Mattox for closing remarks.

Keri P. Mattox

Former Senior Vice President of Investor Relations & Corporate Affairs

Thank you, operator, and thank you all for joining us for today's call.

Operator

Ladies and gentlemen, thank you for your participation in today's conference. That does conclude the program. You may now all disconnect.

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